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REVIEW OF THE ADMINISTRATION'S PESTICIDE REFORM PROPOSAL

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Review of the Administration's Pest...

HEARING

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS
AND NUTRITION

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

JUNE 15, 1994

Serial No. 103-77



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U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON AGRICULTURE

Printed for the use of the Committee on Agriculture

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CONTENTS

	Page
Allard, Hon. Wayne, a Representative in Congress from the State of Colorado, opening statement	11
Canady, Hon. Charles T., a Representative in Congress from the State of Florida, prepared statement	19
Response to written questions	21
Emerson, Hon. Bill, a Representative in Congress from the State of Missouri, prepared statement	13
Gunderson, Hon. Steve, a Representative in Congress from the State of Wisconsin, prepared statement	10
Kingston, Hon. Jack, a Representative in Congress from the State of Georgia, prepared statement	15
McKinney, Hon. Cynthia A., a Representative in Congress from the State of Georgia, prepared statement	12
Response to written questions	114
Roberts, Hon. Pat, a Representative in Congress from the State of Kansas, opening statement	2
Smith, Hon. Robert F. (Bob), a Representative in Congress from the State of Oregon, opening statement	4
Prepared statement	5
Stenholm, Hon. Charles W., a Representative in Congress from the State of Texas, opening statement	1

WITNESSES

Boillot, James B., executive director, National Agricultural Aviation Association	170
Prepared statement	308
Borman, Earle K., member, biocides panel, Chemical Manufacturers Association	207
Prepared statement	454
Delaney, Tom, director, government affairs, Professional Lawn Care Association of America	217
Prepared statement	496
Doyle, Becky, director, Illinois Department of Agriculture, on behalf of the National Association of State Departments of Agriculture	160
Prepared statement	265
Duggan, Juanita, senior vice president, government affairs, National Food Processors Association	190
Prepared statement	334
Engel, Ralph, president, Chemical Specialties Manufacturers Association	205
Prepared statement	437
Feldman, Jay, executive director, National Coalition Against the Misuse of Pesticides	175
Prepared statement	327
Goldenberg, Norman, past president, National Pest Control Association	214
Prepared statement	487
Goldman, Lynn R. M.D., Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency	27
Prepared statement	225
Gullickson, William D., Jr., chairman, board of directors, Chemical Producers and Distributors Association	197
Prepared statement	394
Hazeltine, William, on behalf of the American Mosquito Control Association ...	219
Prepared statement	502

	Page
Hinkle, Maureen Kuwano, director, agricultural program, National Audubon Society	174
Prepared statement	318
James, Allen, executive director, Responsible Industry for a Sound Environment	213
Prepared statement	477
Karmol, David L., general counsel, National Spa and Pool Institute	221
Prepared statement	513
Lehman, Hon. Richard H., a Representative in Congress from the State of California	158
Prepared statement	261
Lyons, James R., Assistant Secretary, Natural Resources and Environment, U.S. Department of Agriculture	25
Prepared statement	225
Maslyn, Mark A. director, governmental relations, American Farm Bureau Federation	162
Prepared statement	272
Panetta, Joseph, director, regulatory and environmental affairs, Mycogen Corp., also on behalf of the Biotechnology Industry Organization	168
Prepared statement	304
Pflug, Gerald R., president, Soap and Detergent Association	209
Prepared statement	461
Schlect, Christian, chairman, Minor Crop Farmer Alliance, and president, Northwest Horticultural Council	166
Prepared statement	295
Schwartz, Joseph M., associate director, policy, Physicians for Social Responsibility	177
Prepared statement	338
Stenzel, Thomas, president, United Fresh Fruit and Vegetable Association	164
Prepared statement	286
Stickle, Warren E., legislative consultant, International Sanitary Supply Association	211
Prepared statement	465
Taylor, Michael R., Deputy Commissioner, Policy, U.S. Food and Drug Administration	29
Prepared statement	225
Vroom, Jay J., president, National Agricultural Chemicals Association	192
Prepared statement	360
Wiles, Richard, director, agricultural pollution prevention, Environmental Working Group	172
Prepared statement	310
Ziller, Stephen, vice president, science and technology, Grocery Manufacturers of America, Inc	195
Prepared statement	386

SUBMITTED MATERIAL

Baughman, Barbara, colegistative chairman, Women Involved in Farm Economics—WIFE, statement	517
Meyerhoff, Albert H., senior attorney, and Jennifer Curtis, Natural Resources Defense Council, statement	518
National Cotton Council of America, statement	570
Rowland, J. Roy, a Representative in Congress from the State of Georgia, statement	573

REVIEW OF THE ADMINISTRATION'S PESTICIDE REFORM PROPOSAL

WEDNESDAY, JUNE 15, 1994

**HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT
OPERATIONS AND NUTRITION,
COMMITTEE ON AGRICULTURE,
*Washington, DC.***

The subcommittee met, pursuant to call, at 8:35 a.m., in room 1300, Longworth House Office Building, Hon. Charles W. Stenholm (chairman of the subcommittee) presiding.

Present: Representatives Brown, Sarpalius, Dooley, Inslee, Glickman, McKinney, Volkmer, Holden, Farr, Johnson, Pomeroy, Lambert, Smith of Oregon, Gunderson, Allard, Barrett, Ewing, Kingston, and Canady.

Also present: Representative E (Kika) de la Garza, chairman of the committee, and Representative Pat Roberts, ranking minority member of the committee.

Staff present: Joseph Muldoon, associate counsel; William E. O'Conner, Jr., minority policy coordinator; John E. Hogan, minority counsel; Dale Moore, minority legislative coordinator; Glenda L. Temple, clerk; Stan Ray, James A. Davis, Joe Dugan, Curt Mann, and Pete Thomson.

OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM. The subcommittee will come to order. In order to accommodate the large number of those interested in providing this subcommittee with input on the administration's proposal this morning, we originally had this hearing broken into 2 days. However, due to scheduling conflicts, we unfortunately had to cancel yesterday's hearing and are forced to try to squeeze everything into 1 day. And that is why we are starting a little earlier than normal.

In our continuing effort to move this issue forward, I am extremely interested in now laying the administration's proposal next to the others, currently on the table, so that it might receive full review and consideration.

Although I recognize the complexity of these issues and appreciate the efforts of the respective agencies to produce a comprehensive package, I am somewhat discouraged that we are only now receiving this legislation, 7 months after my subcommittee held hearings to review the administration's intentions. We should have been moving forward many months ago, not in the later stages of the 103d Congress.

Today's agricultural community is extremely sensitive to the environmental and consumer impact of bringing food and fiber to the rest of the Nation. The farmer knows that he or she is successful only to the extent that the consumer is satisfied.

Our task, however, is to ensure that these decisions are achieved through sound practical science, not temporary emotional appeal or unnecessary and unfunded Government mandates. Although we are blessed with and often take advantage of a tremendous wholesome food supply, today's society demands and deserves an updated legal framework by which to regulate that food supply.

From improving efficiencies in the regulatory process to ensuring consumers that there is no significant risk associated with our Nation's food and fiber, improvements can and should be made.

I am prepared to move swiftly to review the details of this proposal and to work cooperatively with other committees of jurisdiction, the full Agriculture Committee and this administration in bringing the necessary changes to the floor of the House as soon as possible.

At this time, I would recognize Mr. Roberts.

OPENING STATEMENT OF HON. PAT ROBERTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. ROBERTS. Good morning, Mr. Chairman.

I have a prepared statement full of calm and reasoned summarizing of this legislative effort. I will get to that in just a moment, but first this word, sir.

Never say that this subcommittee is not accommodating in regard to trying to arrange our schedule to certainly suit the many players in this legislative effort. In discussing this with Secretary Lyons, I am pleased that he survived his "red-eye" transportation to accommodate us on this subcommittee.

I must say though, Mr. Chairman, that your enthusiasm and your positive attitude about having hearings on FIFRA at 8:30 in the morning is somewhat akin to other joys in this world like caning, reruns of 1 minute's on C-SPAN, and other such endeavors. However, I was informed by Administrator Goldman that she has to deal with FIFRA every day. That is not a negligible risk. We ought to arrange for hazardous-duty pay for the Administrator if, in fact, that is the case.

Sixteen years ago, back in the dark ages as a staffer here, I was assigned to cover a FIFRA hearing when the legislative assistant in charge of such was sick. I came back and informed my predecessor, Mr. Keith Sebelius, that if there was one issue I did not want to cover again, it was FIFRA.

And here we are, both you and I, still riding that trail. I don't know who is driving the stage and who is riding shotgun, but we are still trying to get FIFRA out of the chute, and get that animal saddled and get on beyond.

So I hope we can reach some conclusion today, and I thank you for holding the hearing.

And I thank all the witnesses for being here early as we try to address what is wrong. This is going to be an exhaustive, not to mention an exhausting review of the key proposals involved in this debate.

The chairman has mentioned the time that has passed between the administration's testimony last September and the introduction of the bills in May. I have some concerns, fueled by an abundance of these preliminary drafts that have arisen, and I am a little concerned that the administration's language was substantially changed. The reason I use the word "concerned" is that I think most of the changes have seemed to be geared toward making life a little tougher for farmers and ranchers.

I do recognize that some of the concerns involve many provisions where acceptable compromises or basic clarifications can reasonably be worked out. At the same time, staff reviews of both H.R. 4329, H.R. 4362, indicate many of the tougher issues still remain unresolved.

The administration's proposal still phases out the consideration of benefits on food-use pesticides, including benefits that have a positive impact on consumer's public health and the environment. It adds new overlapping and confusing administrative enforcement authorities, sunset, phase-down/phase-out, label call-in, to existing authority.

It significantly expands recordkeeping provisions for farmers and other certified applicators, while exempting those who use a substantial volume of "off-the-shelf" pesticides used in urban areas. That is one issue I am tired of, restrictions in farm country and that are not the same standards with regard to urban areas.

It subordinates FIFRA to FFDCA, which effectively would allow pesticides to be regulated through their respective FFDCA-established tolerances, while ignoring the regulatory safeguards contained in FIFRA. It does not contain provisions for national uniformity. Mr. Stenholm and I have fought that fight many sessions in the past.

It provides for citizen suits that will keep EPA tied up in court defending deadline and other nuisance suits, as well as subjecting at least part of production agriculture to potentially lengthy and expensive litigation that likely could put them out of business.

I think the issue before us is this: We, meaning the Subcommittee and the full Agriculture Committee, have a multitude of problems, questions and concerns in regard to the administration's proposal. What do we suggest then—since it is our responsibility—as an avenue to address these concerns and from what position of strength do we base our arguments? The answer is a package called H.R. 1627.

From the beginning, the Members and special interests involved in putting this package together tried to recognize the need to work with the administration, Members of Congress, and interest groups, to sort out the details, or in some cases, omissions of our proposal. Speaking for myself, I remain ready and willing to do just that.

I do want to point out that H.R. 1627 now enjoys 221 cosponsors in the House and the companion bill over in the Senate has over 20 sponsors. These numbers I think clearly demonstrate our interest and desire to be full partners in constructing a reform package that is fair and cognizant of the very critical need to maintain a rational balance between the risks and the benefits of pesticides and their uses.

Just as important, it must be recognized that undertaking a constructive meaningful reform of Federal pesticide policies should be a calm, reasoned and deliberative process. But again, I am—indeed all of us involved in production agriculture are—committed and willing to undertake this task.

So while I have listed my concerns and observations in regard to the administration proposal, I look forward to working with the administration and with everyone interested and involved in this debate.

And, Mr. Chairman, I thank you for your determined perseverance and leadership on this particular issue.

End of statement.

Mr. STENHOLM. Thank you, Mr. Roberts. Mr. Smith.

OPENING STATEMENT OF HON. ROBERT F. (BOB) SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. SMITH of Oregon. Mr. Chairman, if there is ever a committee in the Congress that is supposed to be friendly to agriculture, it has to be this one. And we are faced with a real dilemma here in that agriculture and this committee believe that we need safe food, and we do, and we believe that we need the tools that are inherent with pesticides and herbicides to assist production agriculture to make it productive, to continue for this country to be the chief food supplier that it is to our people and the safest food supplier to our people, and yet we continually face these questions about who is the enemy. And many times the enemy is our own Government.

If you look around our country these days, we have lost the old ancient enemy, the Soviet Union, but now we are being attacked by our own Government, and that is us here around this table. So we have an awesome responsibility, it seems to me, to on the one hand, being the only residue of protection of agriculture, that is us, but also being responsible for providing for, in some cases, for changes in the methodology by which we practice agriculture.

So as we go through this, I would hope and I believe that this committee will continue to be the spokes entity for agriculture, and that we will continue to seek methods and ways to improve production agriculture and to be helpful to the farmer, not the enemy.

I have several reservations about the administration's bill, phase-out/phase-down authorities, registration sunsets, citizen suits, the elimination of benefits and risk assessment on food use, pest controls and others. But I am willing, Mr. Chairman, to sit with you, as I always have, and try to work through these programs.

I, too, am a cosponsor of H.R. 1627, which I believe is a middle-of-the-road direction for improvement. But we will go through, as we have with patience, the administration's proposal.

Hopefully, there will be some improvements that we can make. And I want to cooperate with you, Mr. Chairman, in any efforts that you want and take as long as you want.

Thank you for the opportunity.

[The prepared statement of Mr. Smith of Oregon follows:]

STATEMENT OF
ROBERT F. SMITH
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
JUNE 14, 1994

Mr. Chairman, I'd like to thank you for calling this hearing today. While this Administration package was originally announced almost nine months ago, I am pleased to finally see the details of the Administration's pesticide policy proposal. I welcome Assistant Secretary Jim Lyons, Assistant Administrator Lynn Goldman and Deputy Commissioner Michael Taylor and thank them for coming here to outline President Clinton's proposal.

As I stated during that hearing last September, I will be examining the President's proposal according to his own yardstick: putting people first. In other words, how will this proposal ensure that we have an adequate, wholesome and economical food supply? In my reading of the legislation, I cannot imagine how it could achieve this goal.

Woven throughout the legislation is the theme of the Environmental Protection Agency shirking its regulatory responsibility by shifting the burdens from itself to the very individuals it regulates. This theme manifests itself in numerous ways.

The role of benefits in our nation's pesticide policy has been all but eliminated. In its place are "time-limited transitional tolerances" of no more than five years if the loss of the pesticide would result in "significant disruption of food supply."

The consideration risks associated with pest control technologies would never be questioned because its good common sense. Though the techniques of risk assessment are evolutionary, complex and open to debate, we accept the challenge because we have no choice.

Benefits assessment is just as complex and challenging as risk assessment. To simplify the problem of pesticide regulation, many would have us dismiss benefits altogether, saying we should not be interested in the profits of farmers and chemical companies. Such a narrow benefits standard does an injustice to the nutritional welfare of consumers, the budgets of low income shoppers, and the economic well being of all in this nation involved in food production from farm to table.

The role of benefits in the regulation of pest controls should not be eliminated in order to lighten the work of bureaucrats or to ease the agenda of environmental interest groups. I regret the Administration's decision to virtually ignore the role of benefits in risk assessment.

President Clinton has proposed a registration sunset in which pesticide registrations and tolerances would require renewal every 15 years. Data would have to be in by year 12, even if EPA decides a new, five year study is necessary in year eleven. This adds regulatory cost and additional economic risks to pest control methods and agricultural production.

As I read the legislation, if the registration were not renewed by the end of the 15 year deadline, a one year extension could be granted. At the end of that year, according to the language in the bill, the registration of that chemical would simply disappear. So, if EPA fails to act, or if its own roadblocks prevent the registrant from meeting the deadline, farmers loose the use of safe chemical products and consumers suffer the economic burden associated with the resultant disruption in food production. Responsibility is shifted away from EPA.

A new phase-out authority would allow the EPA to use an easier standard than the cancellation procedure to gradually and effectively cancel use of chemicals based on "credible scientific evidence". A major problem with this idea is the definition of "credible scientific evidence". What does this mean? For example, would the evidence rejected by the EPA's Scientific Advisory Panel regarding Alar be considered "credible"?

Once again, I believe EPA is trying to lower the bar for itself. While I support giving EPA improved suspension and cancellation authority, like that contained in HR 1627, so that the can remove protect human health and the environment, I cannot see any justification to give them the ill-defined, but potent ability to simply eliminate existing pest control technologies at its whim.

In addition to my concern that it would encourage EPA to circumvent the FIFRA cancellation process, I believe that some sort of gray area for pesticide registration status is irresponsible. A chemical is either safe for use or it isn't. To further confuse the issue by instituting a "phase-out" does a disservice to producers, possessors and consumers. With "phase-out" the EPA may just want a tool it can use to manage public opinion disasters, but it will come at the expense of sound public policy.

The Administration's pesticide policy proposal would extend current Farm Bill pesticide recordkeeping requirements on restricted use chemicals to all chemicals, for farmers only. At the same time in the proposal to amend the Federal Food, Drug and Cosmetic Act, the EPA would be required to assess and identify non-dietary exposure in the home, water, lawn, work place, and elsewhere, and include these exposures in setting food use tolerances.

Simply stated, agriculture's ability to use a chemical on a farm, where it can be controlled and measured, would ultimately be limited by other uses which cannot be controlled or measured on a national basis. This prompts me to ask: if non-dietary exposures are going to be considered in tolerance setting, why not extend recordkeeping to all uses of chemicals?

The legislation includes a provision under FIFRA which would give individual private citizens standing to file suits regarding enforcement of pesticide regulations on farms. Rather than accept the responsibility Congress has granted to enforce pesticide law and regulation, EPA is seeking to shift the responsibility away from itself.

And, in a very ill-advised provision, EPA would grant any citizen the right to sue any federal official that did not meet one of the countless deadlines EPA would have us add to the law. Given EPA's record on meeting deadlines, this is a curiously self-destructive proposal.

The idea of civil suits may appeal to some on a simplistic level. However, it strikes right at the heart of government's role in our society and can be terribly disruptive. The government is charged with the responsibility to arbitrate among the needs of all its citizens. Individuals do not often share this view, which is why it is absurd to give them such broad power to disrupt public policy. Ask the tens of thousands of unemployed timber workers about the good intentions of individuals seeking their own policy agenda in the nation's courtrooms.

I would find it difficult to seriously consider accepting legislation with so many major faults. However, I am still interested in hearing the witnesses' testimony on President Clinton's pesticide proposal.

In closing, I would like to point out that legislation already exists that represents a balanced solution for federal pesticide policy.

HR 1627, the Food Quality Protection Act, currently enjoys 220 cosponsors, from the House Committee on Agriculture, from the House Committee on Energy and Commerce and among the membership of the House. I would like to add that this is up by over 100 cosponsors since the Administration unveiled its proposal last September. HR 1627 still enjoys widespread support from the agriculture and food processing community, with endorsements from over 230 organizations.

HR 1627 would provide the EPA the regulatory authority needed to more quickly eliminate the use of pesticides under the cancellation process, and remove time consuming paperwork constraints that have in the past slowed EPA efforts to prohibit the use of pesticides in emergency situations.

The Delaney Clause, while well-intentioned 34 years ago, has become an anachronism that must be replaced by a sound standard of negligible risk. If the Administration hopes to play a significant role in developing a resolution, their proposal is going to have to be much more realistic in this area.

In any event, this will be a long and difficult process. In the meantime, I would like remind the Administration witnesses that this Committee has demonstrated time and again its confidence in the Executive by incorporating considerable discretionary authority into our legislation. I think I can speak for my colleagues in saying that we expect these

authorities to be used to resolve, not create, crisis for our nation's farmers, ranchers and consumers.

Again, Mr. Chairman, thank you for calling this hearing. I look forward to hearing the testimony of our witnesses and listening to their answers from this panel.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. I think I will pass, Mr. Chairman.

Mr. STENHOLM. Mr. Gunderson.

Mr. GUNDERSON. Mr. Chairman, at 9:30 I've got to go over to the Education and Labor Committee to continue marking up a health care bill, so in the interest of time, I am going to ask that a statement be inserted in the record.

But I would like to pose one question, which I hope becomes the guiding light for discussions today to all the witnesses. And that is: How do we get from here to there, and in particular, those of you in the administration, how can you help us achieve or develop the compromise necessary to pass legislation so we don't repeat this ad infinitum in the next session and beyond?

Thank you.

[The prepared statement of Mr. Gunderson follows:]

PREFARED STATEMENT OF HON. STEVE GUNDERSON

It was my understanding after the hearing last September that Administrator Browner, representing a new Administration, wanted to bring a resolution to the issues surrounding the use of pesticides. However, after a perusal of the Administration's recommendations, it appears today that we are even further from a "compromise" regarding pesticides.

In an effort to establish a compromise, where does the Administration acknowledge the benefit of pesticides? Current law takes into account the impact of the loss of a pesticide that enables us to provide an adequate, wholesome and economical food supply. The cosponsors of the Lehman/Bliley/Roland Bill, acknowledge that pesticides, though they produce a residue, also protect humans from adverse effects on public health....yes... fungicides are necessary to kill molds and mildews which are parasites on living organisms.

While we have a responsibility to protect public health, are we going to ignore the fact that the unavailability of a pesticide could limit production, thus the consumption of fruits and vegetables so necessary in peoples' diets....particularly for growing children. Do you acknowledge that the loss of the use of pesticides will cause a decline in crop yield per acre. Economics 101 in college taught me that the less of a supply you have of something, the higher the price on the commodity you desire. Are low-income families going to find fresh fruit and vegetables prohibitive to buy? And what about the safety of farmers and farm workers? Some replacement pesticides leave significant less residue on foods, but are more acutely toxic to farmers and applicators.

John Graham of the Harvard Center of Risk Analysis states, "Like all complex technologies in daily life, the responsible application of pesticides will inevitably present some risks that can only be justified by an informed, explicit, and accountable assessment of their benefits. Where do you acknowledge the beneficial use of pesticides? Where is the compromise?

Mr. STENHOLM. Mr. Inslee.

Mr. INSLEE. I will pass, Mr. Chairman.

Mr. STENHOLM. Mr. Canady.

Mr. CANADY. No statement.

Mr. STENHOLM. Mr. Canady.

Mr. CANADY. I have no opening statement.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. Looking forward to the witness' testimony, Mr. Chairman.

Mr. STENHOLM. Mr. Allard.

OPENING STATEMENT OF HON. WAYNE ALLARD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Mr. ALLARD. Mr. Chairman, I do have a few comments. Sorry about the misunderstanding and thank you for recognizing me.

I would like to associate my remarks with both of my ranking members on this side, Mr. Roberts and Mr. Smith, as well as Mr. Gunderson. I would just add to those remarks that this particular member in particular would like to see an emphasis on good scientific-based decision-making.

I think that is extremely important and I have talked with other members of this committee that feel that is also important in whatever we discuss here.

In addition to that, there needs to be a spectrum of common sense that is brought in. So not only do we look at the scientific facts, but we look at how the scientific information is being applied so that we can provide a safe supply of food that is of high quality and we can continue to produce in sufficient quantities to not only feed this country but also to meet the needs of the world. So I think the challenge before this committee is to focus on science and to bring a commonsense approach to what we know to be fact.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Glickman.

Mr. GLICKMAN. No statement.

Mr. STENHOLM. All members, both present and those yet to come, their entire written statements will be made a part of the record at this point in the record.

[The prepared statements of Ms. McKinney, Mr. Emerson, Mr. Kingston, and Mr. Canady follow:]

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Good Morning Mr. Chairman and thanks for holding this important hearing on pesticides. I believe this is very important to our communities and to the people of this world.

I believe we need to do more to help our farmers reduce their use of pesticides.

We need legislation to provide farmers with the opportunity to diversify their approach to pest control. Present programs are under-funded, under-utilized and have failed to control the rise of chemical use. Despite increased attention in the early 80's to the health and environmental risks posed by agri-chemicals, chemical use has increased. Currently, 67 known carcinogenic pesticides are used on food grown on U.S. farms. New research indicates that certain pesticides can disrupt the immune and endocrine systems in animals, with implications for human health. The Environmental Protection agency has detected 46 pesticides in the ground water of 26 states as a result of normal farm usage.

Clearly, we must change the way we farm.

- ★ We need legislation that reverse this course by having farmers play an integral role in designing reductions programs. For example, establish regional councils to allow farmers to demonstrate pesticide reduction techniques based on regional cropping systems. Identify model farms in each region to showcase reduction techniques, and require comprehensive record-keeping and reporting of pesticide use to allow for measurement of progress.

Farmers are looking to Congress for support and guidance on this important issue. Recent polls indicate that the American people support programs to reduce the use of pesticides.

Again, thank you Mr. Chairman for holding this hearing and I look forward to working with this subcommittee on this important issue.

BILL EMERSON
MEMBER OF CONGRESS
8TH DISTRICT, MISSOURI

HOUSE COMMITTEE ON
AGRICULTURE
HOUSE COMMITTEE ON
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STATEMENT OF CONGRESSMAN BILL EMERSON
BEFORE THE HOUSE AGRICULTURE DEPARTMENT OPERATIONS
AND NUTRITION SUBCOMMITTEE
REVIEW OF THE ADMINISTRATION'S PESTICIDE REFORM PROPOSAL
JUNE 15, 1994

Mr. Chairman, I wish to thank you and the Ranking Member, Mr. Smith, for holding this important forum on the Clinton Administration's pesticide reform plan. More specifically, I hope today that we can further examine the basis of current risk-assessment methodologies for pesticide uses and the effectiveness of the current pesticide regulatory processes as the American farmer continues to produce the safest and most abundant food supply in the world. Indeed, we must also highlight the many positive benefits that accrue for the world's consumers through the use of pesticides in the production of food and fiber by our nation's farmers and ranchers.

For some time now, there has been a great deal of concern regarding the federal government's ability to protect American consumers and the environment from potential dangers posed by the use of pesticides. This has also lead to the Administration's ill-conceived effort to expand Environmental Protection Agency (EPA) authority for removing or suspending pesticides from the market. Unfortunately, we are still witnessing professional environmentalists, along with the proliferation of "consumer" zealots, who would fan the flames of public paranoia through tainted information or half-truths which ultimately poses a threat to a system that needs to rely more on scientific accuracy than Hollywood actresses for hire.

I have supported several legislative solutions that promote responsible science through testing and research. To do this right, it may take time but the interests of our nation's consumers deserve the facts -- not fear. As we deal with the perpetual "doomsayers", we must pursue legislative solutions that indeed achieves the balance between the tools of agricultural production and the interests of the consuming public.

I would also like to stress to those unfamiliar with common agricultural practices, particularly in this Administration -- that the abundance of wholesome, affordable food that the American consumer takes for granted would not be possible without the responsible use of pesticides. Improving the regulatory process through responsible science will help separate reality from irrationality and emotional distortion.

Certainly, science holds the key to unlocking the answers to many of the difficult challenges of pesticide methodology. The task before researchers is vast and complicated. Before significant changes in pesticide use can occur, new ways of thinking must be tested. Likewise, reliable information must be made available in order to make rational decisions applicable to mainstream agriculture.

Finally, I certainly believe that we must protect our natural resources, our environment and the men, women, and children who live in our rural communities and depend upon agriculture for our livelihood. We must have solid, iron-clad evidence before the fears of farmers and consumers are needlessly compounded. Reliable information is the key and common-sense must prevail.

Opening Statement
 Honorable Jack Kingston
 Wednesday, June 15, 1994

 PUBLIC HEARING
 HOUSE COMMITTEE ON AGRICULTURE
 DEPARTMENT OPERATIONS & NUTRITION SUBCOMMITTEE
 FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

Throughout its history, the United States has been a low-cost producer of agricultural products. Consumers have been the primary beneficiaries, as the percentage of disposable income spent on food has steadily declined for more than forty years. **Americans today enjoy a standard of living unparalleled in the world . . . even those in what we call the "lower income brackets" can afford what many in the "upper middle classes" of most other countries cannot afford. *The biggest reason for this is the availability to U.S. families and consumers of the highest quality, safest, most nutritious food supply in the history of mankind — and at the lowest prices anywhere in the world.***

In June of 1993, the Clinton Administration announced its commitment to "significantly, and even drastically" reducing the use of pesticides in all aspects of Americans' lives. This, we have been told, is the basis for their current legislative proposal. As EPA Administrator Carol Browner has said, "Since pesticides are risky, less

Hon. Jack Kingston
F.I.F.R.A. Statement
June 15, 1994
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is better." This overly simplistic – and almost childish view – naively ignores realities that exist in the world in which the rest of us must live and raise our families. While no specific provision in the bill mandates the reduced use of pesticides, I believe provisions such as Ms. Browner's "label call-in, phase-out/phase-down," and the Administration's refusal to consider the overall benefits of a pesticide in regulating tolerances will directly result in their short-sighted goal of removing these overwhelmingly beneficial tools from our production inventory.

Also, Mr. Chairman, the economics of regulation is an issue I believe we must consider. What do the economics of unjustified, scare-tactic pesticide use restriction mean to the average American? Recent studies indicate the social return on investment in pest control products is very high for our consumers and farm producers. One study has indicated that a \$1 investment in pesticide control will return \$4 in increased crop yields, based on a total of \$2.2 billion spent on controlling pests saving \$9 billion worth in crops. Other studies indicate that pesticides generate about \$6 in additional output per dollar spent. Still other analyses indicate even higher returns, when the effects on the quality of the crop is taken into account. Bottom line –

*Hon. Jack Kingston
F.I.F.R.A. Statement
June 15, 1994*
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the wise use of pesticides gives farmers the ability to continue producing high quality, inexpensive food to improve Americans' living standards and health.

Other studies have examined the impact of not using pesticides and various use-reduction scenarios. The results of the studies have been dramatic. Last summer, researchers at Texas A&M released a study on the consequences of reduced pesticide use on fruits and vegetables. The results were quite alarming for Georgia peach growers. The study found that a 50% reduction in pesticide use would result in a 100% loss of commercial yields! Can this be justified because, as Ms. Browner says simplistically, "less is better."?

Farmers are not the only ones who suffer from willy-nilly "less is better"-type regulations. As I stated in the beginning, consumers have been the primary beneficiary of our Great American Food Machine. USDA estimates Americans on average spend about 12.5 percent of their disposable income for food items. If the Administration's overly zealous and scientifically unsound agenda is adopted, American families can expect to pay 50% to 100% more for the food they now take for granted. Further, U.S. taxpayers can expect to see the costs of

Hon. Jack Kingston
F.I.F.R.A. Statement
June 15, 1994
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our Food Stamp, School Lunch, WIC, and other feeding programs also increase dramatically since it will take more money to help provide such benefits in the future due to increases in food costs.

The Federal Food, Drug and Cosmetic Act requires that EPA "give appropriate consideration" to the "necessity for the production of an adequate, wholesome and economical food supply." This concept is carried over in H.R. 1627 and is a sound and reasonable approach to regulating pesticides. This provision could hardly be construed as a major regulatory hurdle for the agency, nor could it be construed as compromising the safety of consumers. Quite the contrary, an adequate, wholesome and economical food supply is in the public's best interest, the realities of which I have already described. Yet, to my amazement, the Administration's proposal calls for the elimination of this type of consideration. It would seem this is more in the interest of reducing the agency's workload than in improving public health. I am anxious to hear the Administration's rationale for this proposal, and look forward to working with my Colleagues on the committee to ensure the future availability, affordability, and safety of America's food supply.

— END —

S T A T E M E N T O F

REP. CHARLES T. CANADY

PESTICIDE REFORM PROPOSALS HEARING

SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

JUNE 15, 1994

Mr. Chairman, let me thank you for holding this hearing and allowing us the opportunity to examine several of the proposals before Congress to reform our pesticide and food safety laws. I look forward to hearing the testimony of the witnesses.

We in the United States have the safest and most affordable food on the planet. All of us share the goal of ensuring that this remains so. Our food safety laws play a vital role in ensuring that our citizens do not have to worry about the safety of the food they eat.

Emerging technologies, more advanced and sophisticated testing equipment and new methods of food production have all contributed to making our current food safety laws out of date. The Delaney Clause, for example, enacted in the 1950s, has proved too cumbersome and unwieldy for effective enforcement in the 1990s. There is a real need for reform in this and several other areas on which we all can agree.

Mr. Chairman, since early last year the Congress has been engaged and ready to go to work on this issue. Representatives Lehman, Bliley and Rowland have worked with the members of this Committee and many others in crafting a comprehensive reform of our nation's pesticide policy. This bill has attracted 220 cosponsors. It enjoys widespread support from the agriculture and food processing industries as well as many of the farmers in my district.

The Administration, however, has only recently submitted to Congress the proposal we are examining today. This package greatly expands the regulatory scope of the Environmental Protection Agency, shifts the burden of satisfying regulatory constraints from EPA to the industry, subordinates Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) regulation to the tolerances set in the much broader Federal Food, Drug and Cosmetic Act (FFDCA), provides for unlimited fee authority and eliminates the consideration of benefits in the regulation of pesticides.

These features of the Administration's proposals are troubling to me and to the farmers in my district. The difficulties of complying with ever increasing and ever-more-costly federal mandates --- many of which have little benefit to society at large --- are a common source of complaint in the

FOOD SAFETY LEGISLATION HEARING
PAGE TWO

agricultural community.

I am also concerned about the treatment under this bill of minor food use pesticides. A new and higher fee structure that does not take into account the special needs of minor use pesticides will lead to even more disincentives for manufacturers to invest in these chemicals.

Mr. Chairman, there is much we can do here in Congress to bring our food safety policy in line with current technology and farming practices. We can take care of the Delaney problem and solve the minor use problem without unduly expanding the regulatory powers of the federal government. There is much we can do without increasing the burdens carried by our farmers.

I look forward to the testimony of the witnesses and working with the members of the Subcommittee on this issue. I also have several written questions for the Administration witnesses which I will insert in the record.

Thank you, Mr. Chairman.

U.S. ENVIRONMENTAL PROTECTION AGENCY'S ANSWERS TO
 REPRESENTATIVE CHARLES T. CANADY'S QUESTIONS
 FROM JUNE 15, 1994 HEARING
 SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
 U.S. HOUSE OF REPRESENTATIVES

1. I am concerned about the removal of the consideration of benefits when establishing or revoking pesticide registrations. It appears to me that your bill subjugates sound risk/benefit concepts in FIFRA to the EPA's risk-only standard. What are your reasons for denying the consideration of a pesticide's benefits?
- A. The Administration is proposing a change in the risk-benefit standards for pesticide residue tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). Our proposal would establish a uniform, health-based standard for setting tolerances (maximum permissible levels) for pesticide residues in food, consistent with the recommendations of the National Academy of Sciences and others. Pesticide uses which result in residues that do not meet the FFDCA standard would not be registered, consistent with EPA's current policies.

In setting tolerances under current law, EPA must consider the necessity of the pesticide for the production of an adequate, wholesome, and economical food supply. We are proposing that pesticides will be regulated according to a single standard that will ensure "a reasonable certainty of no harm" to consumers of food. The result should be enhanced public confidence in food safety and our regulatory system.

Our experience to date leads us to conclude that excluding consumer and producer benefits from consideration will not cause major problems. While these economic benefits have played a role in our decisions, we have never had a case where both benefits and risks from residues were substantial, because to date, substitute pesticides have been available in all cases where dietary risk has been a concern, so that economic benefits have not been large. We cannot predict how reregistration will affect the availability of substitutes. We have allowed a transitional period of up to 5 years to maintain flexibility in the event of major disruptions while the adjustment to any new methods of pest control is taking place. USDA and EPA will increase efforts to ensure that agricultural producers will have access to effective means of pest control.

2. Under your bill, products which carry the label "animal carcinogen" will be regulated as "human carcinogens," even in cases in which the scientific data indicates that the risk is irrelevant for humans. It seems to me that this is another Delaney-type problem where products in which ever-smaller traces of animal carcinogen in a product would require the product to be regulated as human carcinogen. Is this the case?
- A. No. The Administration's proposals are designed to ensure adequate flexibility to allow improvements in the science base of EPA's decisions and to permit risk assessment methodologies to change as scientific knowledge about potential risks advances over time.

Specifically, with respect to potential carcinogens, the bill states that any tolerances established for "pesticides found to induce cancer when ingested by humans or animals or determined on the basis of reliable scientific evidence to pose a potential dietary risk of cancer in humans" must pose no more than "negligible risk."

In the case you cite, if EPA were able to reach the "scientific conclusion that the animal carcinogenicity data were not relevant to humans, the agency would be able to set tolerances for the pesticide that would meet the negligible risk standard. By contrast, under a Delaney-type approach, no tolerances could be established, even if the risks were negligible.

3. I would like a better understanding of your intentions with regard to the protection of children. Will there be separate tolerances for food products (such as baby food or infant) that are marketed solely for infants and small children? Or will the tolerance structure for the entire spectrum of foods be geared to those levels that will bring the least harm to children?
- A. Under the Administration's proposals, EPA would be required to make a specific safety finding for children whenever it establishes or reestablishes a tolerance. This proposed requirement means that all tolerances will be set at a level that is protective for children, taking into account their dietary consumption patterns and what is known about their potential sensitivity to the pesticide residue. It is not our intent to set separate tolerances for adults and children; rather a single tolerance for the food in question will be established that is protective for children, as well as for other significant subpopulations.

The Administration's proposals also explicitly provide for the establishment of tolerances for foods at different

stages in the chain of food production and distribution. For example, where necessary to ensure the safety standard is met, EPA could set one tolerance for raw agricultural commodities at the farmgate, and a lower tolerance for finished or processed food products. In some cases, EPA could establish tolerances specific to the food forms consumed by children that would differ from the tolerances that apply to raw foods at the farmgate.

4. **Won't the limitations on tolerance extensions have the greatest adverse impact on minor uses since there are fewer economic incentives to develop alternatives for those uses?**
- A. The Administration's proposals specifically recognize the need to provide incentives for the development and maintenance of registrations for pesticide minor uses.

These incentives include priority review and extended exclusive data use rights. In reregistration, unsupported minor uses lacking only residue chemistry data could continue until the last study for the pesticide is due, and registrants would have until that date to supply data for the minor use.

EPA will also be working with USDA and the Department of Health and Human Services/Public Health Service to identify key agricultural and public health pesticide uses that could be lost, and to target research to ensure that needed pest control tools are available to farmers and other pesticide users.

5. **Have you decided on a fee structure for pesticide registration and renewal? Are you considering a separate fee structure for minor food use pesticides? If they are the same, wouldn't the new fees in your bill provide even more disincentives for manufacturers to invest in the development of minor use pesticides?**
- A. The Administration's proposals for periodic registration renewal ("sunset") include general fee authority to help support this new program. The fee structure has not been specifically defined, and a number of options are possible, for example, annual fees on active ingredients or annual pesticide registration maintenance fees on a pesticide product basis.

In general, data development costs and other priorities appear to have figured more prominently in manufacturers' decisions about which pesticide uses to maintain. To the extent that fees would have significant adverse effects on minor uses, the Administration could consider waivers and other alternatives to alleviate this problem. Currently,

the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) contains provisions for reduction or waiver of certain fees, and we look forward to working with Congress to explore the best statutory framework for the new fees.

Mr. STENHOLM. And we are now happy to call the first panel.

The first witness is the Honorable James R. Lyons, Assistant Secretary for Natural Resources and Environment.

Mr. Lyons.

**STATEMENT OF JAMES R. LYONS, ASSISTANT SECRETARY,
NATURAL RESOURCES AND ENVIRONMENT, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY LARRY ELWORTH, SPECIAL ASSISTANT FOR PESTICIDE POLICY**

Mr. LYONS. Thank you, Mr. Chairman, Mr. Smith, and members of the subcommittee. I am pleased to have the opportunity to appear before you today to discuss many of the issues that are all too familiar to you Mr. Chairman, Mr. Smith, Mr. Roberts and others of the subcommittee.

Of the many difficult and controversial issues the Agriculture Committee and this subcommittee has faced over the years, the debate over pesticides has certainly proved to be one of the most contentious and at times intractable. It is a debate in which good intentions are rarely rewarded and compromises are hard to come by, you all know that.

A number of us in the Clinton administration knew this ahead of time as well. Despite the ground rules for debate over FIFRA and pesticide reform, we decided to dive in and take on the work of devising what we hope will serve as the basis for a resolution in these long pending issues.

Despite the inevitable difficulties, we believe that the problems in our current pesticide laws are to the detriment of agricultural producers and consumers alike, and serve the joint efforts of the agencies with responsibilities in pesticide reform. We proposed a comprehensive set of amendments to FIFRA, to FFDCA, because our regulatory system simply does not guarantee consumers confidence in the safety of our food supply, because it contains conflicting and archaic standards, and because it fails to ensure that producers have the necessary new tools to raise their crops in an environmentally and economically sound manner.

There is a wide array of opinions as to the safety of pesticide residues in the food supply. For its part, the Department of Agriculture has conducted programs to increase the amount and quality of reliable information available for assessing exposure to pesticides.

However, one does not have to believe that there is an imminent health hazard from pesticide residues to concede that agricultural producers continue to experience a great deal of vulnerability, in the marketing of their products, from consumer concern about pesticides. Neither producers or consumers benefit from a regulatory system that fails to inspire public confidence, characterized by lengthy and cumbersome procedures for eliminating unacceptable risks.

The administration's legislation contains specific provisions as are designed to result in timely decisions based on sound science and the use of reliable data, such as consideration of the percent of crop treated in setting tolerances. Court-mandated enforcement of the Delaney clause in FFDCA has drawn most of the attention

in anticipation of possibly significant negative impacts on producers.

The effects of this enforcement can be seen not only in the potential loss of 409 and 408 tolerances for a wide array of uses. The cloud which Delaney has cast over regulatory decisionmaking has had a negative impact on moving important new uses through the registration process and has deterred registrants from investing in promising new uses that might get tied up in Delaney issues. The situation has significant negative impacts on producers and registrants alike.

Given that these impacts are the result of legal complications and do not necessarily improve public health or safety, neither producers or consumers benefit from the effects of Delaney. For this reason, the administration has proposed a single narrative negligible risk standard as the best method to ensure public health, protect the diets of infants and children, and provide the necessary flexibility for science to evolve.

As concerned as we are about the need to remove unreasonable risks that may be posed by pesticides, we have also proposed to deal with the problems in the current system that impede the availability to agriculture of the tools necessary to produce marketable and abundant products. The administration's legislation provides significant incentives for the development and registration of minor-use and reduced-risk alternatives and establishes deadlines for action on registration petitions for new alternatives, in addition to providing for rational regulatory options for minor-use and biological pesticides.

The truth is that when we cancel the use for an important pest, the pest does not go away. We must ensure that producers can economically manage serious pests and respond to new pest problems. The focus must be on the need for pest management and our regulatory system must respond to that need by recognizing that new alternatives should be registered to meet environmental and agricultural needs. Even without statutory changes, USDA has begun the process of making integrated pest management a more important priority within its research and education programs.

The administration has maintained that a vital economy and environmental protection can and should go hand in hand. It is up to us to make certain that our programs provide producers with the tools to make that possible.

Mr. Chairman, I know that you and the other members here today share the concerns that have led the administration to take on this debate over pesticides. Experience has shown us that the problems will not be solved by rhetorical flourishes.

In the final analysis, fair and legitimate resolution will be the result of hard work and commitment that you and other Members of Congress, and particularly of this subcommittee, will bring to the table to finally attempt to resolve these difficult issues. Your leadership in convening this hearing as a means of forging resolution in this controversy is greatly appreciated. Even though time is limited in this Congress, this is a mature debate that will get no easier to resolve in the future.

We are willing to work with you, subcommittee members and everyone who has a stake in this debate, to attempt to produce sound

and lasting legislative reforms that will be a service to agriculture, public health, and the environment.

I appreciate the opportunity to be with you this morning.

Mr. STENHOLM. Next, Lynn R. Goldman, Assistant Administrator for Office of Pesticides and Toxic Substances, EPA.

Dr. Goldman.

STATEMENT OF LYNN R. GOLDMAN, M.D., ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY JIM AIDALA

Dr. GOLDMAN. Thank you, Chairman Stenholm, Mr. Smith, and subcommittee members. I am pleased to appear before you today to discuss the major pesticide food safety legislation pending before your subcommittee.

We do appreciate your initiative in scheduling these hearings and your continued interest in working with us to complete the important task of legislative reform in this Congress. I especially want to thank you for your flexibility in scheduling this hearing today.

As you know, the administration has submitted legislative proposals that were introduced last month into the House of Representatives and the Senate as the Pesticide Reform Act of 1994, and the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1994.

Today we want to review the goals stated last fall by Administrator Browner, Commissioner Kessler, and Deputy Secretary Rominger. The need for legislation is no less urgent than it was last fall.

We believe that the administration's approach offers the most comprehensive proposal available for meeting that need. First, however, I would like to review the agency's efforts to comply with the 9th Circuit Court of Appeals ruling on the Delaney clause.

As you are aware, the court requires that EPA interpret and apply the Delaney clause literally. Since then, we have taken action to revoke the food additive regulations for the pesticides that were involved in the Delaney litigation. Again, within the next month or so, I will be signing a proposal to revoke food additive regulations involving an additional 13 pesticides, and 28 crops, and we continue to comply with the court ruling.

Chart 1 lists the crops, pesticides and States that are potentially affected by the court ruling. As you can see, the impacts are potentially very large.

The need for legislative reform, however, goes beyond the Delaney clause. The National Academy of Sciences' report, "Pesticides in the Diets of Infants and Children," the report of the Administrative Conference of the United States, and testimony by this administration are all witnesses to the need for fundamental change in the laws governing pesticides.

The administration's bills are grounded on two principles: Fundamental change and transition.

Fundamental change: We need to create a pesticide regulatory system that does more than just react to the Alars and the EDB's,

a system that anticipates problems and deals with them before they take on a life of their own.

In instance after instance, the inability or unwillingness of the Government to take strong regulatory action in the face of significant risks has resulted in financial harm to the regulated industry. In the case of pesticides, the growers and the manufacturers are usually hit hardest.

In 1988, Congress took a step in the right direction with the reregistration program. But we need to go further. Reregistration is an excellent program that has resulted in regulatory actions affecting thousands of products and hundreds of pesticides. However, this critical program is in desperate need of additional funds.

The next two charts show how long public health and environmental safety decisions will be delayed unless the proposed new fee authorities are enacted. It is time now to provide the agency with the regulatory tools to ensure this information we received as part of reregistration can be dealt with in a timely manner.

Our cancellation, suspension, phase-down and label call-in proposals are no more than a collection of regulatory tools that are necessary to adequately protect human health and the environment in a timely manner. In designing these tools, we have balanced the need for timely action with the need to protect the rights of the growers and the chemical industry.

As you can see from the next chart, H.R. 1627 does not provide the EPA with these tools. In effect, H.R. 1627 simply tries to respond to today's problem with 1980's solutions, with only one tool available for all jobs.

Additionally, the cancellation provision in H.R. 1627 is significantly more complex than the administration's proposal. We estimate it would add 1 to 2 years to the process we have proposed, with no added value.

There are two other FIFRA provisions in our bill that I would like to mention. The first is the sunset provision. The report on "Pesticides in the Diets of Infants and Children" should remind us that science changes over time.

Our sunset provision requires EPA and the registrants to update all pesticide registrations every 15 years. Sunset will ensure that we are never again in the position of having registered pesticides that have not received a safety review in zero to 40 years.

Separately, we need to update the enforcement provisions of FIFRA. All too often, a small number of FIFRA violators, whether they be manufacturers, applicators, or growers, achieve an unfair competitive advantage over their law-abiding competitors because of FIFRA's weak enforcement authorities. It is time to put the violators at a disadvantage.

While I am on the subject of fundamental change, it would be an oversight not to discuss the FFDCA proposals that we put forward. We propose to replace the three incompatible standards governing pesticide residues on food, including the zero-risk standard of the Delaney clause, with a single health-based standard of a reasonable certainty of no harm.

This administration strongly believes that pesticide residues on food should be safe, especially for children. We also believe that most pesticides currently on the market will meet this standard.

However, pesticides that cannot meet a safety standard should not be on the market.

Transition: The second theme of our bill is transition. Transition from a system that reacts to a system that acts, a system that can be completely overtaken by a chain of events to a system that takes actions to prevent both damage to public health and damage to the regulated community.

Our proposal also offers a transition from older more dangerous chemicals to newer chemicals and methods of pest control. From a system designed to protect old and often dangerous chemicals to one that is designed to help farmers with providing better pest control practices.

To ensure an orderly transition from the existing regulatory system to a new health-based system, we have provided a 10-year transition. If the loss of a pesticide were to result in a significant disruption in domestic production, EPA could grant a transitional tolerance.

The executive branch needs to be more involved in helping growers who have few or no alternatives to control pests. Our FIFRA proposal requires the kind of coordination and cooperation between the EPA and the USDA to ensure that growers have the pest control methods they need.

In summary, I believe it is critical that we work to move beyond adversarial debate and to seek to identify practical approaches that serve the legitimate interests of all concerned. This has been the administration's goal in developing its proposals.

I want to thank you again for your initiative in conducting these hearings and I appreciate the willingness of this subcommittee and others in Congress to work with the administration to enact meaningful reforms as soon as possible.

Mr. STENHOLM. Next, Mr. Michael Taylor, Deputy Commissioner for Policy, Food and Drug Administration.

Mr. Taylor.

STATEMENT OF MICHAEL R. TAYLOR, DEPUTY COMMISSIONER, POLICY, U.S. FOOD AND DRUG ADMINISTRATION

Mr. TAYLOR. Mr. Chairman, Mr. Smith, and members of the subcommittee. I appreciate the opportunity to appear before you today with my colleagues from EPA and USDA to discuss the important topic of pesticide food safety reform.

Setting and enforcing standards to ensure the safety of food is one of the oldest and most basic functions of Government. This is because people are unwilling and unable to fend for themselves in the market place when it comes to obtaining safe food for their families.

Today's consumer demands that the Government set sound science-based food safety standards and that systems be in place to ensure those standards are met. Consumers realize there are no absolute guarantees when it comes to food safety. But they rightly expect when they go to the supermarket that everything that reasonably can be done by Government and the food industry to ensure the safety of food has been done. Public opinion polls illustrate this point.

In a 1992 survey conducted for the Grocery Manufacturers of America, 80 percent of consumers expressed a desire for tighter food safety standards. The Food Marketing Institute also reported in 1992 that 76 percent of consumers consider pesticide residues a serious hazard.

So, Mr. Chairman, public concern about food safety is real. We know that. And that is one reason why the Clinton administration has made such a strong commitment to food safety reform.

The three agencies before you today are working together to make sure that all of our food safety standards are up to date and fully protective, and we are modernizing our systems of food inspection to be sure that we and the food industry are capitalizing on the best available science and technology to detect and prevent food safety hazards.

In this effort, pesticides demand special attention. It is no secret that the existing system of pesticide regulation is seriously flawed. To be sure, we are not in the midst of a food safety crisis when it comes to pesticides. But the system falls short of providing the American public the assurance they seek that everything that can reasonably be done is being done to ensure the safety of pesticide residues in food.

The problems are well documented. We have standards for setting pesticide tolerances that are confused and conflicting. Many tolerances are old and not based on up-to-date science. And the procedural barriers to swift action by EPA make it difficult to address new food safety concerns about marketed pesticides as rapidly as the public has a right to expect.

I think we can all agree, Mr. Chairman, that the question before Congress today is not whether there is a need for reform of our pesticide laws. The need is genuine and widely recognized. The question is whether we can achieve real reform, reform that corrects the defects in current law and meets the food safety expectations of the American people.

The essential elements of real reform are simple. We need a consistent health-based safety standard that fully protects infants and children as well as adults. We need to bring all existing pesticides into compliance with that standard without undue delay. And we need to be able to address promptly new or newly discovered food safety problems.

The Clinton administration has worked for more than a year to develop realistic legislation that contains these elements. This legislation would establish for all pesticide residues the same "reasonable certainty of no harm" safety standard that food additives must meet. It would establish a realistic but enforceable timetable for bringing all pesticides into compliance with this standard. And it would give EPA the tools it needs under FIFRA to address emerging problems promptly and effectively.

The administration bill has ample procedural protections for pesticide manufacturers and others who depend on particular pesticides. It also recognizes that the Government has an obligation not only to act against pesticides that cause problems, but also to work with growers, pesticide manufacturers, and the scientific community to foster development of safer pesticides and alternative

pest control agents so that the needs of American agriculture continue to be met.

But make no mistake, Mr. Chairman, the administration bill would adjust the balance of our pesticide laws toward the consumer. It would introduce to FIFRA the principle that when safety questions exist about a pesticide, the burden of proof should not rest solely on the EPA, and the burden of uncertainty and delay should not rest solely on the consumer.

Rather, the burden to resolve the issues should shift to the manufacturer. This is only fair. It is what people expect, and it is one important reason why the administration's bill represents real food safety reform.

Mr. Chairman, the issues in pesticide reform legislation are complex. They are difficult. But we do think the time has come to reform a system of regulation whose successful functioning is so vital to all Americans.

The administration's bill provides a viable vehicle for reform, and we look forward to working with this subcommittee and the many groups that have a stake in the outcome of this legislation to achieve real reform of our Nation's pesticide laws.

Thank you, Mr. Chairman. I look forward to your questions.

[The prepared statement of Dr. Goldman, Mr. Lyons, and Mr. Taylor appears at the conclusion of the hearing.]

Mr. STENHOLM. I thank each of you for your testimony this morning.

I might have to start the clock. We would like to operate under the 5-minute rule. We will take a second round if necessary and perhaps a third round if necessary this morning.

The first question that I was supposed to ask you is why it has taken so long to get a bill put together? I will not ask you that question.

I would note, though, the absence of television cameras this morning. I want to ask a question, a show of hands, is there anyone from the tabloid TV in the audience?

Anybody from "60 Minutes," "20/20," "48 Hours," "Prime Time?" If so, please show your hand.

Mr. VOLKMER. Really not interested, Mr. Chairman.

Mr. STENHOLM. Well, let the record show, Mr. Taylor, as you talked about the need of food safety and the sincere concerns of all of those who, as others have said this morning, in the producing side of agriculture, we are sincerely interested in getting some solutions to the problem.

The problem we have is that there are those that are not interested in solutions, they are interested in issues. And I won't call for a show of hands of the rest of the folks that fit in that category that are in the audience this morning, but I would note the absolute absence for the record.

And I notice that there is quite a few of the written press here this morning, which we are appreciative of. This is part of our problem. And it is a big part of our problem, and it is why we have such difficulty getting to solutions.

First question I would like to ask is after all of the deliberation over the last months and this subcommittee waiting patiently from

last September until today for this day to arrive, why did you send us two bills instead of one?

Dr. GOLDMAN. Basically, I think that you have two bills instead of one is because we felt that both of the statutes that deal with pesticides and food safety are in need of reform. We believe that the FFDCA statute is in need of reform because of the dual-food safety standard within that statute, and the lack of attention in that statute to provide adequate protections for infants and children and adequate enforcement authorities for the FDA, as Mr. Taylor explained.

We also believe that FIFRA is in need of reform. And with me today I brought for the record some copies of some of the, I think, very influential work that led us to these conclusions.

First, the executive summary from the National Academy of Sciences report, "Pesticides in the Diets of Infants and Children," which speaks to the need for reform in the FFDCA law.

And second, the report from the Administrative Conference of the United States on the regulatory procedures and administrative procedures at the EPA which speaks to the need for reform of our administrative procedures under FIFRA at the EPA.

Mr. STENHOLM. Without objection, those will be made a part of the record.

[The information follows:]

PESTICIDES *in the* **DIETS OF INFANTS** **AND CHILDREN**

Committee on Pesticides in the Diets of
Infants and Children

Board on Agriculture
and
Board on Environmental Studies and Toxicology

Commission on Life Sciences

National Research Council

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Preface

IN 1988, THE U.S. CONGRESS requested that the National Academy of Sciences establish a committee within the National Research Council to study scientific and policy issues concerning pesticides in the diets of infants and children. The Committee on Pesticide Residues in the Diets of Infants and Children appointed to undertake this study was charged with responsibility for examining what is known about exposures to pesticide residues in the diets of infants and children, the adequacy of current risk assessment methods and policies, and toxicological issues of greatest concern. The committee operated under the joint aegis of the Board on Agriculture (BA) and the Board on Environmental Studies and Toxicology (BEST).

The committee first met in October 1988 and held its last meeting in January 1993. Several full committee meetings were held each year, and subgroups of the committee were convened on a number of occasions to address such topics as the physiology of infants and children, the age-specific patterns of children's diets, the measurement of residue levels, and the mathematical modeling of risks. The expertise represented on the committee included pediatrics, toxicology, epidemiology, biostatistics, food science and nutrition, analytical chemistry, and child growth and development. When required, advice was obtained from experts outside the committee on a variety of topics.

Critical assessment of potential risks to health resulting from exposures to toxicants in the environment has been the focus of several recent studies conducted by BEST and BA. Many of the approaches to risk assessment used in this report trace their origins to the reports on *Drinking Water and*

Health developed since 1977. Of particular value was Volume 6 in that series. The committee also found useful *Risk Assessment in the Federal Government: Managing the Process* (1983), *Biologic Markers in Reproductive Toxicology* (1989), *Biologic Markers in Immunotoxicology* (1992), and *Environmental Neurotoxicology* (1992). The analysis in this volume draws conceptually from the 1987 report from the Board on Agriculture called *Regulating Pesticides in Food: The Delaney Paradox*—an examination of the process by which levels of pesticide residues in foods are regulated by the U.S. Government.

The Committee on Pesticides in the Diets of Infants and Children was greatly assisted by many individuals and groups who provided information on food consumption patterns and on pesticide residue concentrations in the U.S. diet. The groups include the U.S. Department of Agriculture, the U.S. Food and Drug Administration, the National Food Processors Association, the Gerber Products Company, and the Infant Formula Council. Many other food manufacturers as well as pesticide manufacturers also provided useful data to the committee either individually or through various organizations.

The committee is grateful for the assistance of the National Research Council (NRC) staff in the preparation of this report. In particular the committee wishes to acknowledge Frances Peter, project manager; Richard Thomas, principal staff scientist (BEST); Sandi Fitzpatrick, senior program assistant (BEST); James Reisa, director of BEST; and Susan Offutt, executive director of BA. Other staff members who contributed to this effort include Shelley A. Nurse, senior project assistant (BEST); Ruth P. Danoff, project assistant (BEST); Craig Cox, senior staff officer (BA); Mary Lou Sutton, administrative assistant (BA); Carla Carlson, director of communications (BA); Barbara J. Rice, editor (BA); Janet Overton, associate editor (BA); Lee R. Paulson, program director for information systems and statistics (BEST); Bernidean Williams, information specialist (BEST); and Dawn M. Eichenlaub, production manager, and Richard E. Morris, editor, National Academy Press. Thanks are also due to Richard Wiles and Charles Benbrook, formerly of the BA staff. The interest in this report shown by the Executive Office of the National Research Council, especially by the Deputy Executive Officer Mitchel Wallerstein, is greatly appreciated. These individuals provided invaluable support to the committee throughout its deliberations.

As consultant to the committee, John Wargo of the Yale University School of Forestry and Environmental Studies developed numerous innovative approaches to the analysis of highly complex data. His pellucid presentations permitted clear understanding of issues that previously had been opaque. Valuable assistance was also provided to the committee by Emmanuel Akpanyie, Sheryl Bartlett, and Judy Hauswirth, who served as technical advisers.

Last, but by no means least, the work of all the members of the committee is greatly appreciated. We are also grateful to the U. S. Environmental Protection Agency, Health and Welfare Canada, the International Life Sciences Institute, and the Kellogg Endowment Fund of the National Academy of Sciences and the Institute of Medicine, whose financial support made the study possible.

PHILIP J. LANDRIGAN, M.D., M.Sc.
Chairman

Contents

EXECUTIVE SUMMARY	1
1 BACKGROUND AND APPROACH TO THE STUDY	13
Pesticide Use, 14	
Pesticide Control Legislation, 17	
Approach to the Study, 18	
References, 22	
2 SPECIAL CHARACTERISTICS OF CHILDREN	23
Growth, 25	
Development, 36	
Conclusions and Recommendations, 42	
References, 44	
3 PERINATAL AND PEDIATRIC TOXICITY	49
Acute Toxicity, 49	
Neurotoxicity, 60	
Immunotoxicity, 66	
Carcinogenesis and Mutagenesis, 70	
Metabolism and Pharmacokinetics, 76	

	Scaling and Progression Analysis, 96	
	Conclusions and Recommendations, 105	
	References, 110	
4	METHODS FOR TOXICITY TESTING	127
	Current Methods: General Considerations, 128	
	Acute Toxicity Studies, 133	
	Subchronic Toxicity Studies, 137	
	Chronic Toxicity Studies, 145	
	Developmental Toxicity Studies, 146	
	Reproduction Studies, 147	
	Mutagenicity Studies, 150	
	General Metabolism Studies, 150	
	Neurotoxicity Studies, 151	
	Special Testing, 152	
	Conclusions and Recommendations, 152	
	References, 156	
5	FOOD AND WATER CONSUMPTION	159
	Food Consumption Surveys, 159	
	Survey Methodology, 161	
	Survey Design, 164	
	Sample Weights, 167	
	Sample Size, 167	
	Comparisons of Intake Data with Standards, 167	
	Validation of Food Consumption Data, 168	
	The Strengths and Weaknesses of the Food	
	Consumption Data Bases in Estimating Pesticide	
	Exposure of Children, 169	
	Water Intake, 172	
	Quantification of Consumption Data, 177	
	Age-Related Differences in Dietary Patterns, 181	
	Issues Related to the Evaluation of Food Monitoring	
	Data, 194	
	Conclusions and Recommendations, 195	
	References, 197	
6	PESTICIDE RESIDUES	203
	Sources of Data on Usage, 203	

The Occurrence and Fate of Pesticide Residues, 206	
Pesticide Registration and the Development of Analytical Methods, 207	
Methods for Sampling and Analysis, 210	
Monitoring, 215	
Quality Controls, 223	
Limitations of the Data, 224	
Pesticides in Water, 227	
Pesticides in Infant Formula, 232	
Pesticides in Human Milk, 239	
Pesticides in Foods, 244	
Conclusions and Recommendations, 260	
References, 263	

7 ESTIMATING EXPOSURES 267

The Use of Food Consumption and Residue Data for Exposure Assessment, 270	
Long-Term Exposure to Benomyl, 277	
Short-Term Exposure to Aldicarb, 287	
Multiple Exposure Assessment: Organophosphate Insecticides, 297	
Nondietary Exposure to Pesticides, 307	
Conclusions and Recommendations, 314	
References, 319	

8 ESTIMATING THE RISKS 323

General Principles of Risk Assessment, 324	
Risk Assessments for Infants and Children, 339	
Conclusions and Recommendations, 359	
References, 363	

INDEX 373

Executive Summary

PESTICIDES ARE USED WIDELY in agriculture in the United States. Their application has improved crop yields and has increased the quantity of fresh fruits and vegetables in the diet, thereby contributing to improvements in public health.

But pesticides may also cause harm. Some can damage the environment and accumulate in ecosystems. And depending on dose, some pesticides can cause a range of adverse effects on human health, including cancer, acute and chronic injury to the nervous system, lung damage, reproductive dysfunction, and possibly dysfunction of the endocrine and immune systems.

Diet is an important source of exposure to pesticides. The trace quantities of pesticides that are present on or in foodstuffs are termed residues. To minimize exposure of the general population to pesticide residues in food, the U.S. Government has instituted regulatory controls on pesticide use. These are intended to limit exposures to residues while ensuring an abundant and nutritious food supply. The legislative framework for these controls was established by the Congress through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Pesticides are defined broadly in this context to include insecticides, herbicides, and fungicides.

Tolerances constitute the single, most important mechanism by which EPA limits levels of pesticide residues in foods. A tolerance is defined as the legal limit of a pesticide residue allowed in or on a raw agricultural commodity and, in appropriate cases, on processed foods. A tolerance must be established for any pesticide used on any food crop.

2. PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN

Tolerance concentrations are based primarily on the results of field trials conducted by pesticide manufacturers and are designed to reflect the highest residue concentrations likely under normal conditions of agricultural use. Their principal purpose is to ensure compliance with good agricultural practice. Tolerances are not based primarily on health considerations.

This report addresses the question of whether current regulatory approaches for controlling pesticide residues in foods adequately protect infants and children. The exposure of infants and children and their susceptibility to harm from ingesting pesticide residues may differ from that of adults. The current regulatory system does not, however, specifically consider infants and children. It does not examine the wide range of pesticide exposure patterns that appear to exist within the U.S. population. It looks only at the average exposure of the entire population. As a consequence, variations in dietary exposure to pesticides and health risks related to age and to such other factors as geographic region and ethnicity are not addressed in current regulatory practice.

Concern about the potential vulnerability of infants and children to dietary pesticides led the U.S. Congress in 1988 to request that the National Academy of Sciences (NAS) appoint a committee to study this issue through its National Research Council (NRC). In response, the NRC appointed a Committee on Pesticide Residues in the Diets of Infants and Children under the joint aegis of the Board on Agriculture and the Board on Environmental Studies and Toxicology.

The committee was charged with responsibility for examining scientific and policy issues faced by government agencies, particularly EPA, in regulating pesticide residues in foods consumed by infants and children. Specifically, the committee was asked to examine the adequacy of current risk assessment policies and methods; to assess information on the dietary intakes of infants and children; to evaluate data on pesticide residues in the food supply; to identify toxicological issues of greatest concern; and to develop relevant research priorities. Expertise represented on the committee included toxicology, epidemiology, biostatistics, food science and nutrition, analytical chemistry, child growth and development, and pediatrics.

The committee was not asked to consider toxicities resulting from exposures to microorganisms (bacteria and viruses) or from other naturally occurring potential toxins. It was not asked to weigh the benefits and risks to be derived from a plentiful and varied food supply against the potential risks resulting from pesticide exposure. It was not asked to assess the overall safety of the food supply.

In this report, the committee considered the development of children from the beginning of the last trimester of pregnancy (26 weeks) through

18 years of age, the point when all biological systems have essentially matured.

CONCLUSIONS

Age-Related Variation in Susceptibility and Toxicity

A fundamental maxim of pediatric medicine is that children are not "little adults." Profound differences exist between children and adults. Infants and children are growing and developing. Their metabolic rates are more rapid than those of adults. There are differences in their ability to activate, detoxify, and excrete xenobiotic compounds. All these differences can affect the toxicity of pesticides in infants and children, and for these reasons the toxicity of pesticides is frequently different in children and adults. Children may be more sensitive or less sensitive than adults, depending on the pesticide to which they are exposed. Moreover, because these processes can change rapidly and can counteract one another, there is no simple way to predict the kinetics and sensitivity to chemical compounds in infants and children from data derived entirely from adult humans or from toxicity testing in adult or adolescent animals.

The committee found both quantitative and occasionally qualitative differences in toxicity of pesticides between children and adults. Qualitative differences in toxicity are the consequence of exposures during special windows of vulnerability—brief periods early in development when exposure to a toxicant can permanently alter the structure or function of an organ system. Classic examples include chloramphenicol exposure of newborns and vascular collapse (gray baby syndrome), tetracycline and dysplasia of the dental enamel, and lead and altered neurologic development.

Quantitative differences in pesticide toxicity between children and adults are due in part to age-related differences in absorption, metabolism, detoxification, and excretion of xenobiotic compounds, that is, to differences in both pharmacokinetic and pharmacodynamic processes. Differences in size, immaturity of biochemical and physiological functions in major body systems, and variation in body composition (water, fat, protein, and mineral content) all can influence the extent of toxicity. Because newborns are the group most different anatomically and physiologically from adults, they may exhibit the most pronounced quantitative differences in sensitivity to pesticides. The committee found that quantitative differences in toxicity between children and adults are usually less than a factor of approximately 10-fold.

The committee concluded that the mechanism of action of a toxicant—how it causes harm—is generally similar in most species and across age

and developmental stages within species. For example, if a substance is cytotoxic in adults, it is usually also cytotoxic in immature individuals.

Lack of data on pesticide toxicity in developing organisms was a recurrent problem encountered by the committee. In particular, little work has been done to identify effects that develop after a long latent period or to investigate the effects of pesticide exposure on neurotoxic, immunotoxic, or endocrine responses in infants and children. The committee therefore had to rely mostly on incomplete information derived from studies in mature animals and on chemicals other than pesticides.

The committee reviewed current EPA requirements for toxicity testing by pesticide manufacturers, as well as testing modifications proposed by the agency. In general, the committee found that current and past studies conducted by pesticide manufacturers are designed primarily to assess pesticide toxicity in sexually mature animals. Only a minority of testing protocols have supported extrapolation to infant and adolescent animals. Current testing protocols do not, for the most part, adequately address the toxicity and metabolism of pesticides in neonates and adolescent animals or the effects of exposure during early developmental stages and their sequelae in later life.

Age-Related Differences in Exposure

Estimation of the exposures of infants and children to pesticide residues requires information on (1) dietary composition and (2) residue concentrations in and on the food and water consumed. **The committee found that infants and children differ both qualitatively and quantitatively from adults in their exposure to pesticide residues in foods.** Children consume more calories of food per unit of body weight than do adults. But at the same time, infants and children consume far fewer types of foods than do adults. Thus, infants and young children may consume much more of certain foods, especially processed foods, than do adults. And water consumption, both as drinking water and as a food component, is very different between children and adults.

The committee concluded that differences in diet and thus in dietary exposure to pesticide residues account for most of the differences in pesticide-related health risks that were found to exist between children and adults. Differences in exposure were generally a more important source of differences in risk than were age-related differences in toxicologic vulnerability.

Data from various food consumption surveys were made available to the committee. In analyzing these data, the committee found it necessary to create its own computer programs to convert foods as consumed into their component raw agricultural commodities (RACs). This analytic ap-

proach facilitated the use of data from different sources and permitted evaluation of total exposure to pesticides in different food commodities. For processed foods, the committee noted that effects of processing on residue concentrations should be considered, but that information on these effects is quite limited. Processing may decrease or increase pesticide residue concentrations. The limited data available suggest that pesticide residues are generally reduced by processing; however, more research is needed to define the direction and magnitude of the changes for specific pesticide-food combinations. The effect of processing is an important consideration in assessing the dietary exposures of infants and young children, who consume large quantities of processed foods, such as fruit juices, baby food, milk, and infant formula.

Although there are several sources of data on pesticide residues in the United States, the data are of variable quality, and there are wide variations in sample selection, reflecting criteria developed for different sampling purposes, and in analytical procedures, reflecting different laboratory capabilities and different levels of quantification between and within laboratories. These differences reflect variations in precision and in the accuracy of methods used and the different approaches to analytical issues, such as variations in limit of quantification. There also are substantial differences in data reporting. These differences are due in part to different record-keeping requirements, such as whether to identify samples with multiple residues, and differences in statistical treatment of laboratory results below the limit of quantification.

Both government and industry data on residue concentrations in foods reflect the current regulatory emphasis on average adult consumption patterns. The committee found that foods eaten by infants and children are underrepresented in surveys of commodity residues. Many of the available residue data were generated for targeted compliance purposes by the Food and Drug Administration (FDA) to find residue concentrations exceeding the legal tolerances established by the EPA under FFDCA.

Survey data on consumption of particular foods are conventionally grouped by broad age categories. The average consumption of a hypothetical "normal" person is then used to represent the age group. However, in relying solely on the average as a measure of consumption, important information on the distribution of consumption patterns is lost. For example, the high levels of consumption within a particular age group are especially relevant when considering foods that might contain residues capable of causing acute toxic effects. Also, geographic, ethnic, and other differences may be overlooked.

To overcome the problems inherent in the current reliance on "average" exposures, the committee used the technique of statistical convolution (i.e., combining various data bases) to merge distributions of food consumption

with distributions of residue concentrations. This approach permits examination of the full range of pesticide exposures in the U.S. pediatric population. As is described in the next section, this approach provides an improved basis over the approach now used for assessing risks for infants and children.

A New Approach to Risk Assessment for Infants and Children

To properly characterize risk to infants and children from pesticide residues in the diet, information is required on (1) food consumption patterns of infants and children, (2) concentrations of pesticide residues in foods consumed by infants and children, and (3) toxic effects of pesticides, especially effects that may be unique to infants and children. If suitable data on these three items are available, risk assessment methods based on the technique of statistical convolution can be used to estimate the likelihood that infants and children who experience specific exposure patterns may be at risk. To characterize potential risks to infants and children in this fashion, the committee utilized data on distributions of pesticide exposure that, in turn, were based on distributions of food consumption merged with data on the distribution of pesticide residue concentrations. The committee found that age-related differences in exposure patterns for 1- to 5-year-old children were most accurately illuminated by using 1-year age groupings of data on children's food consumption.

Exposure estimates should be constructed differently depending on whether acute or chronic effects are of concern. Average daily ingestion of pesticide residues is an appropriate measure of exposure for assessing the risk of chronic toxicity. However, actual individual daily ingestion is more appropriate for assessing acute toxicity. Because chronic toxicity is often related to long-term average exposure, the average daily dietary exposure to pesticide residues may be used as the basis for risk assessment when the potential for delayed, irreversible chronic toxic effects exists. Because acute toxicity is more often mediated by peak exposures occurring within a short period (e.g., over the course of a day or even during a single eating occasion), individual daily intakes are of interest. Examining the distribution of individual daily intakes within the population of interest reflects day-to-day variation in pesticide ingestion both for specific individuals and among individuals.

Children may be exposed to multiple pesticides with a common toxic effect, and estimates of exposure and of risk could therefore be improved by accounting for these simultaneous exposures. This can be accomplished by assigning toxicity equivalence factors to each of the compounds having a common mechanism of action. Total residue exposure is then estimated

by multiplying the actual level of each pesticide residue by its toxicity equivalence factor and summing the results. This information may be combined with data on consumption to construct a distribution of total exposure to all pesticides having a common mechanism of action. To test this multiple-residue methodology, the committee estimated children's acute health risks resulting from combined exposure to five members of the organophosphate insecticide family. This was accomplished by combining actual food consumption data with data on actual pesticide residue levels.

Through this new analytical procedure, the committee estimated that for some children, total organophosphate exposures may exceed the reference dose. Furthermore, although the data were weak, the committee estimated that for some children exposures could be sufficiently high to produce symptoms of acute organophosphate pesticide poisoning.

Compared to late-in-life exposures, exposures to pesticides early in life can lead to a greater risk of chronic effects that are expressed only after long latency periods have elapsed. Such effects include cancer, neurodevelopmental impairment, and immune dysfunction. The committee developed new risk assessment methods to examine this issue.

Although some risk assessment methods take into account changes in exposure with age, these models are not universally applied in practice. The committee explored the use of newer risk assessment methods that allow for changes in exposure and susceptibility with age. However, the committee found that sufficient data are not currently available to permit wide application of these methods.

RECOMMENDATIONS

On the basis of its findings, the committee recommends that certain changes be made in current regulatory practice. Most importantly, estimates of expected total exposure to pesticide residues should reflect the unique characteristics of the diets of infants and children and should account also for all nondietary intake of pesticides. Estimates of exposure should take into account the fact that not all crops are treated with pesticides that can be legally applied to those crops, and they should consider the effects of food processing and storage. Exposure estimates should recognize that pesticide residues may be present on more than one food commodity consumed by infants and children and that more than one pesticide may be present on one food sample. Lastly, determinations of safe levels of exposure should take into consideration the physiological factors that can place infants and children at greater risk of harm than adults.

- *Tolerances.* Tolerances for pesticide residues on commodities are currently established by the EPA under FIFRA and FFDCA. A tolerance concentration is defined under FFDCA as the maximum quantity of a pesticide residue allowable on a raw agricultural commodity (RAC) (FFDCA, Section 408) and in processed food when the pesticide concentrates during processing (FFDCA Section 409). Tolerance concentrations on RACs are based on the results of field trials conducted by pesticide manufacturers and are designed to reflect the highest residue concentrations likely under normal agricultural practice. More than 8,500 food tolerances for pesticides are currently listed in the Code of Federal Regulations (CFR). Approximately 8,350 of these tolerances are for residues on raw commodities (promulgated under section 408) and about 150 are for residues known to concentrate in processed foods (promulgated under section 409).

The determination of what might be a safe level of residue exposure is made by considering the results of toxicological studies of the pesticide's effects on animals and, when data are available, on humans. Both acute and chronic effects, including cancer, are considered, although acute effects are treated separately. These data are used to establish human exposure guidelines (i.e., a reference dose, RfD) against which one can compare the expected exposure. Exposure is a function of the amount and kind of foods consumed and the amount and identity of the residues in the foods (i.e., Theoretical Maximum Residue Contributions, TMRCs). If the TMRCs exceed the RfD, then anticipated residues are calculated for comparison with the proposed tolerance. The percent of crop acreage treated is also considered. If the anticipated residues exceed the RfD, then the proposed tolerance is rejected, and the manufacturer may recommend a new tolerance level.

Although tolerances establish enforceable legal limits for pesticide residues in food, they are not based primarily on health considerations, and they do not provide a good basis for inference about actual exposures of infants and children to pesticide residues in or on foods.

Tolerances constitute the only tool that EPA has under the law for controlling pesticide residues in food. To ensure that infants and children are not exposed to unsafe levels of pesticide residues, the committee recommends that EPA modify its decision-making process for setting tolerances so that it is based more on health considerations than on agricultural practices. These changes should incorporate the use of improved estimates of exposure and more relevant toxicology, along with continued consideration of the requirements of agricultural production. As a result, human health considerations would be more fully reflected in tolerance levels. Children should be able to eat a healthful diet

containing legal residues without encroaching on safety margins. This goal should be kept clear.

- *Toxicity testing.* The committee believes it is essential to develop toxicity testing procedures that specifically evaluate the vulnerability of infants and children. Testing must be performed during the developmental period in appropriate animal models, and the adverse effects that may become evident must be monitored over a lifetime. Of particular importance are tests for neurotoxicity and toxicity to the developing immune and reproductive systems. Extrapolation of toxicity data from adult and adolescent laboratory animals to young humans may be inaccurate. Careful attention to interspecies differences in pharmacokinetics and metabolism of pesticides and the relative ages at which organ systems mature is essential. It is also important to enhance understanding of developmental toxicity, especially in humans, during critical periods of postnatal development, including infancy and puberty.

- *Uncertainty factors.* For toxic effects other than cancer or heritable mutation, uncertainty factors are widely used to establish guidelines for human exposure on the basis of animal testing results. This is often done by dividing the no-observed-effect level (NOEL) found in animal tests by an uncertainty factor of 100-fold. This factor comprises two separate factors of 10-fold each: one allows for uncertainty in extrapolating data from animals to humans; the other accommodates variation within the human population. Although the committee believes that the latter uncertainty factor generally provides adequate protection for infants and children, this population subgroup may be uniquely susceptible to chemical exposures at particularly sensitive stages of development.

At present, to provide added protection during early development, a third uncertainty factor of 10 is applied to the NOEL to develop the RfD. This third 10-fold factor has been applied by the EPA and FDA whenever toxicity studies and metabolic/disposition studies have shown fetal developmental effects.

Because there exist specific periods of vulnerability during postnatal development, the committee recommends that an uncertainty factor up to the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete. The committee wishes to emphasize that this is not a new, additional uncertainty factor but, rather, an extended application of a uncertainty factor now routinely used by the agencies for a narrower purpose.

In the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children. To validate this presumption,

the sensitivity of mature and immature individuals should be studied systematically to expand the current limited data base on relative sensitivity.

- *Food consumption data.* The committee recommends that additional data on the food consumption patterns of infants and children be collected within narrow age groups. The available data indicate that infants and children consume much more of certain foods on a body weight basis than do adults. Because higher exposures can lead to higher risks, it is important to have accurate data on food consumption patterns for infants and children. At present, data are derived from relatively small samples and broad age groupings, making it difficult to draw conclusions about the food consumption patterns of infants and children. Because the composition of a child's diet changes dramatically from birth through childhood and adolescence to maturity, "market basket" food consumption surveys should include adequate samples of food consumption by children at 1-year intervals up to age 5, by children between the ages of 5 and 10 years, and by children between 11 and 18 years. Food consumption surveys should be conducted periodically to ascertain changes in consumption patterns over time.

- *Pesticide residue data.* To maximize the utility of pesticide residue data collected by various laboratories, the committee recommends the use of comparable analytical methods and standardized reporting procedures and the establishment of a computerized data base to collate data on pesticide residues generated by different laboratories. Reports on pesticide residue testing should describe the food commodity analyzed (whether processed or raw), the analytical methods used, the compounds for which tests were conducted, quality assurance and control procedures, and the limit of quantification of the tests. All findings should be reported, whether or not the residue sought is found.

-In its surveillance of pesticide residues, FDA should increase the frequency of sampling of the commodities most likely to be consumed by infants and children. The residue testing program should include all toxic forms of the pesticide, for example, its metabolites and degradation products.

-Food residue monitoring should target a special "market basket" survey focused toward the diets of infants and children.

-Pesticide field trials currently conducted by pesticide manufacturers in support of registration provide data on variation in residue concentrations associated with different rates and methods of application. Such data should be consulted to provide a basis for estimating potential maximum residue levels.

—More complete information is needed on the effects of food processing on levels of pesticides—both the parent compound and its metabolites—in specific food-chemical combinations potentially present in the diets of infants and children.

- *Risk assessment.* All exposures to pesticides—dietary and nondietary—need to be considered when evaluating the potential risks to infants and children. Nondietary environmental sources of exposure include air, dirt, indoor surfaces, lawns, and pets.

—Estimates of total dietary exposure should be refined to consider intake of multiple pesticides with a common toxic effect. Converting residues for each pesticide with a common mechanism of action to toxicity equivalence factors for one of the compounds would provide one approach to estimating total residue levels in toxicologically equivalent units.

—Consumption of pesticide residues in water is an important potential route of exposure. Risk assessment should include estimates of exposure to pesticides in drinking water and in water as a component of processed foods.

Given adequate data on food consumption and residues, the committee recommends the use of exposure distributions rather than single point data to characterize the likelihood of exposure to different concentrations of pesticide residues. The distribution of average daily exposure of individuals in the population of interest is most relevant for use in chronic toxicity risk assessment, and the distribution of individual daily intakes is recommended for evaluating acute toxicity. Ultimately, the collection of suitable data on the distribution of exposures to pesticides will permit an assessment of the proportion of the population that may be at risk.

Although the committee considers the use of exposure distributions to be more informative than point estimates of typical exposures, the data available to the committee did not always permit the distribution of exposures to be well characterized. Existing food consumption surveys generally involve relatively small numbers of infants and children, and food consumption data are collected for only a few days for each individual surveyed. Depending on the purpose for which they were originally collected, residue data may not reflect the actual distribution of pesticide residues in the food supply. Since residue data are not developed and reported in a consistent fashion, it is generally not possible to pool data sets derived from different surveys. Consequently, the committee recommends that guidelines be developed for consumption and residue data permitting characterization of distributions of dietary exposure to pesticides.

The committee identified important differences in susceptibility to the toxic effects of pesticides and exposure to pesticides in the diet with age

For carcinogenic effects, the committee proposed new methods of cancer risk assessment designed to take such differences into account. Preliminary analyses conducted by the committee suggest that consideration of such differences can lead to lifetime estimates of cancer risk that can be higher or lower than estimates derived with methods based on constant exposure. However, underestimation of risk assuming constant exposure was limited to a factor of about 3- to 5-fold in all cases considered by the committee. Because these results are based on limited data and specific assumptions about the mechanisms by which carcinogenic effects are induced, the applicability of these conclusions under other conditions should be established.

Currently, most long-term laboratory studies of carcinogenesis and other chronic end points are based on protocols in which the level of exposure is held constant during the course of the study. To facilitate the application of risk assessment methods that allow for changes in exposure and susceptibility with age, it would be desirable to develop bioassay protocols that provide direct information on the relative contribution of exposures at different ages to lifetime risks. Although the committee does consider it necessary to develop special bioassay protocols for mandatory application in the regulation of pesticides, it would be useful to design special studies to provide information on the relative effects of exposures at different ages on lifetime cancer and other risks with selected chemical carcinogens.

In addition to pharmacodynamic models for cancer risk assessment, the committee recommends the development and application of physiologically based pharmacokinetic models that describe the unique features of infants and children. For example, differences in relative organ weights with age can be easily described in physiologic pharmacokinetic models; special compartments for the developing fetus may also be incorporated. Physiologically based pharmacokinetic models can be used to predict the dose of the proximate toxicant reaching target tissues, and may lead to more accurate estimates of risk.

In summary, better data on dietary exposure to pesticide residues should be combined with improved information on the potentially harmful effects of pesticides on infants and children. Risk assessment methods that enhance the ability to estimate the magnitude of these effects should be developed, along with appropriate toxicological tests for perinatal and childhood toxicity. The committee's recommendations support the need to improve methods for estimating exposure and for setting tolerances to safeguard the health of infants and children.

Notices

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This section of the **FEDERAL REGISTER** contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Adoption of Recommendations and Statement Regarding Administrative Practice and Procedure

AGENCY: Administrative Conference of the United States.

ACTION: Notice.

SUMMARY: The Administrative Conference of the United States (ACUS) adopted two recommendations at its Forty-Ninth Plenary Session. The recommendations concerning improving the environment for agency rulemaking and procedures for regulation of pesticides. The Conference also adopted one formal statement at the Plenary Session on the right of persons to consult with counsel in agency investigations.

FOR FURTHER INFORMATION: Renee Barnow, 202-254-7020.

SUPPLEMENTARY INFORMATION: The Administrative Conference of the United States was established by the Administrative Conference Act, 5 U.S.C. 591-596. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by federal agencies in carrying out administrative programs, and makes recommendations for improvements to the agencies, collectively or individually, and to the President, Congress, and the Judicial Conference of the United States (5 U.S.C. 594(1)). At its Forty-Ninth Plenary Session, held December 9-10, 1993, the Assembly of the Administrative Conference of the United States adopted two recommendations and one formal statement.

Recommendation 93-4, Improving the Environment for Agency Rulemaking, concerns the federal agency rulemaking process, which has become both increasingly less effective and more time-consuming. To improve the environment for agency rulemaking, the

Conference recommends specific steps that the President, Congress, and the courts should take to eliminate undue burdens on agency legislative rulemaking.

With regard to presidential oversight, ACUS recommends that presidential oversight and review be reserved for the most important rules and that the agencies be given clear policy guidance in a directive, approved by the President, specifying what is required. In addition, the reviewing or oversight entity should avoid, to the extent possible, extensive delays in the rulemaking process. The review process itself should be open to public scrutiny, following guidelines previously developed by the Administrative Conference. With regard to legislatively-imposed constraints, ACUS recommends that Congress should review and rationalize legislatively-mandated rulemaking procedures, and specific proposals are offered for Congress' consideration. ACUS recommends that courts should be sensitive not to require greater justification for rules than necessary. It also advises that a "reasoned statement" that explains the basis and purpose of the rule and addresses significant issues raised in public comments should be adequate for review. Finally, recognizing that rulemaking is not just a product of external constraints, ACUS recommends a number of steps agency managers can take to improve their internal processes.

Recommendation 93-5, Procedures for Regulation of Pesticides, calls for the adoption of a more coordinated and strategic procedural framework for the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") involving the creation of multiple and reinforcing incentives for regulatory compliance by registrants, for timely and accurate decisionmaking by EPA, and for effective public participation. The Conference recommends that EPA promulgate and communicate clear data standards and guidance on the data expected from registrants. ACUS also recommends that Congress authorize EPA to levy administrative civil money penalties upon registrants submitting data that fail to meet previously announced, clear standards. With regard to suspension and cancellation proceedings, which involve scientific data concerning risks and benefits,

ACUS recommends use of informal procedures by which EPA gives registrants detailed reasons for the agency's actions and then provides registrants with sufficient time to file responsive written comments and supporting documentation. However, an opportunity should be provided to allow affected parties to show cause why oral testimony or cross-examination is justified. Among other specific recommendations, ACUS urges Congress to consider giving EPA the authority to use informal procedures to order the phase-down of existing pesticides when there are safer, effective products or practices available.

Statement No. 16, Right to Consult with Counsel in Agency Investigations, addresses the procedures that govern the relationship between a federal agency and persons compelled to appear before the agency in investigations that may lead to civil or criminal prosecution. While addressing certain issues raised in these investigations, the Conference concluded that a uniform set of recommendations concerning agency procedures was not appropriate given the differences among federal agencies in the roles of investigators and the methods by which witnesses or parties appear before agencies.

The full texts of the recommendations and statement are set out in the Appendix below. The recommendations will be transmitted to the affected agencies and, if so directed, to the Congress of the United States. The Administrative Conference has advisory powers only, and the decision on whether to implement the recommendations must be made by each body to which the various recommendations are directed.

Recommendations and statements of the Administrative Conference are published in full text in the Federal Register. In past years Conference recommendations and statements of continuing interest were also published in full text in the Code of Federal Regulations (1 CFR parts 305 and 310). Budget constraints have required a suspension of this practice in 1994. However, a complete listing of past recommendations and statements are published in the Code of Federal Regulations. Copies of all past Conference recommendations and statements, and the research reports on which they are based, may be obtained

from the Office of the Chairman of the Administrative Conference. As explained at 1 CFR 304.2, requests for single copies of such documents will be filed at no charge to the extent that supplies on hand permit.

The transcript of the Plenary Session is available for public inspection at the Conference's offices at Suite 500, 2120 L Street NW., Washington, DC.

Dated: January 25, 1994.

Jeffrey S. Labbers,
Research Director.

Appendix—Recommendations of the Administrative Conference of the United States

The following recommendations were adopted by the Assembly of the Administrative Conference on December 9 and 10, 1993, respectively:

Recommendation 93-4 Improving the Environment for Agency Rulemaking

Informed observers generally agree that the rulemaking process has become both increasingly less effective and more time-consuming. The Administrative Procedure Act does not reflect many of the current realities of rulemaking. The APA's cumbersome "formal rulemaking" procedures are rarely used except in some adjudicative-type rate proceedings. Meanwhile, the APA's simple "informal rulemaking" procedures (set forth in 5 U.S.C. § 553) have been overlain with an increasing number of constraints: Outside constraints imposed by Congress, the President, and the courts, and internal constraints arising from increasingly complex agency management of the rulemaking process.¹ As a result, many federal agencies, faced with unsatisfactory rulemaking accomplishments in recent years, have turned to alternatives such as less formal policy statements or adjudicative orders to achieve regulatory compliance.²

The Conference believes that the environment for agency legislative rulemaking can be improved. This recommendation sets out a coordinated framework of proposals aimed at promoting efficient and effective rulemaking by addressing constraints on the current process that derive from a variety of sources. We present an

integrated approach for improving the rulemaking environment in order to relieve agencies of unnecessary pressures and disincentives relating to rulemaking. We also identify desirable revisions of section 553 relating to legislative rulemaking. In doing so, this recommendation both presents new proposals and incorporates previous Conference recommendations.

Presidential Constraints

We continue to support presidential coordination of agency policymaking as beneficial and necessary.³ We are concerned, however, that, unless properly focused, this additional review may impose unnecessary costs. All recent presidents have undertaken some level of review and coordination of agency rulemaking. Presidential review of rules, as undertaken under various executive orders applied by the Office of Management and Budget and other White House entities, has often required agencies to submit nearly all proposed and final rules to a review process in which the rules are screened and analyzed for consistency with presidential objectives. Some of these objectives have been incorporated into analytical requirements found in separate executive orders.⁴ This screening process can unduly slow the entire system of rulemaking; it can inhibit the growth of the promising consensus-based alternative of negotiated rulemaking;⁵ and it can create undesirable tensions between the reviewing entities and agency policymakers. While these analytical emphases can be rationalized individually, in the aggregate, they can result in redundant requirements, boilerplate-laden documents, circumvention, delays, and clutter in the Federal Register. Although specific presidential review policies have varied among Administrations, these recommendations set forth principles that the Conference believes generally

should govern presidential review of rules.

We therefore recommend that presidential oversight and review be reserved for the most important rules and that the agencies be given clear policy guidance in a directive, approved by the President, specifying what is required. In addition, the reviewing or oversight entity should avoid, to the extent possible, extensive delays in the rulemaking process. The review process itself should be open to public scrutiny—following guidelines previously developed by the Administrative Conference.⁶ The President's policy should encourage planning and coordination of regulatory initiatives, and early dialogue between agencies and the reviewing entity. To this end, the concept of a unified agenda of regulations is a useful tool and should be preserved. We also believe that additional non-APA analytical requirements should be kept to a minimum. The cumulative impact of such requirements on the rulemaking process should be considered before existing requirements are continued or additional ones imposed. We also believe it is useful to periodically reassess the continued viability and relevance of the various presidential directives.⁷

Legislative Constraints

Congress should similarly review and rationalize legislatively-mandated rulemaking procedures. Specifically, we recommend that it refrain, as it generally has done since the 1970s, from imposing program-specific rulemaking requirements that go beyond the APA's basic notice-and-comment procedures.⁸ Statutory "on-the-record" and "hybrid" rulemaking provisions that require adjudicative fact-finding techniques such as cross-examination, or more stringent provisions for judicial review (in particular, use of the "substantial evidence" test instead of the normal "arbitrary and capricious" test), can be unnecessarily burdensome or confusing and should be repealed.⁹ Although

¹ See Conference Recommendation 88-6, "Presidential Review of Agency Rulemaking," 1 CFR 305.88-6 (1993) (applying Presidential oversight to both executive branch and independent agencies).

² Among the mandates reflected in these executive orders are requirements that agency rulemakers include cost-benefit estimates and analyses of the proposed and final rule's impact on federalism, family values, and future litigation, of whether it effects a "regulatory taking," and of other matters. The Conference of course takes no position on the merits of the values underlying these executive orders.

³ See Conference Recommendations 82-4 and 85-5, "Procedures for Negotiating Proposed Regulations," 1 CFR 305.82-4, 305.85-5 (1993); "Negotiated Rulemaking Act of 1990, 5 U.S.C. 561-60.

⁴ See Conference Recommendation 88-6, "Presidential Review of Agency Rulemaking," 1 CFR 305.88-6 (1993) at ¶ 4.

⁵ While the most recent executive order of presidential review of rules generally reflects the views set forth in this recommendation, see Executive Order 12866, 60 Fed. Reg. 81735 (1993), the Conference takes no position on the specifics of that order.

⁶ See Conference Recommendation 76-3, "Procedures in Addition to Notice and the Opportunity to Comment in Informal Rulemaking," 1 CFR 305.76-3 (1993).

⁷ See Conference Recommendation 80-1, "Trade Regulation Rulemaking Under the Magnusson-Moss Warranty—Federal Trade Commission Improvement Act," 1 CFR 305.80-1 (1993).

¹ See generally McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 Duke L. J. 1385 (1991).

² See Conference Recommendation 92-2, "Agency Policy Statements," 1 CFR 305.92-2 (1993), which distinguished "legislative" rules, normally promulgated through notice-and-comment procedures, from interpretive rules and policy statements, which are exempt from such procedures. The present recommendation addresses legislative rulemaking.

additional procedures can sometimes be beneficial—see, e.g., Section 307 of the Clean Air Act (providing additional safeguards for rulemaking with significant economic and competitive effects)¹⁰—they should be imposed only after careful review and attention by Congress to possible unintended consequences. Otherwise, such additions generally should be left to the discretion of individual agencies.¹¹

Similarly, legislatively-imposed time limits on rulemaking, while understandable, can be unrealistic, resulting in either hastily-imposed rules or missed deadlines that undermine respect for the rulemaking process.¹² Legislative deadlines backed by statutory or regulatory “hammers” (mandating, for example, that the proposed rule or some other policy change¹³ automatically take effect upon expiration of the deadline) are particularly undesirable and often counter-productive;¹⁴ they are generally less desirable than the alternative of judicial enforcement of deadlines.¹⁵

Finally, legislation ancillary to the APA that creates additional rulemaking impediments should be reconsidered. Statutes such as the Regulatory Flexibility Act, which requires a special analysis of virtually all rules’ effects on small business, may have laudable intentions, but their requirements are often both too broadly applicable and not sufficiently effective in achieving their goals. If such requirements are imposed, Congress should focus them more narrowly, by, for example, confining their application to significant rules or particular categories of rules.

Judicial Constraints

Other constraints on rulemaking that warrant similar reconsideration have been imposed through judicial review. The APA, in section 706, provides that agency rules may be set aside if they are “arbitrary or capricious,” represent an “abuse of discretion,” or are “otherwise

not in accordance with law.” The evolving scope of judicial review of agency rules, along with the timing of much such review at the pre-enforcement stage, has contributed to what is sometimes an overly intrusive inquiry. This, in turn, has led agencies to take defensive measures against such review. While some tension is an inevitable adjunct of the process of judicial review, we believe that steps can be taken to lessen some of the burdens without loss of effective outside scrutiny of agency rules.

The tendency of some courts to require extra-APA procedures in rulemaking was arrested by the Supreme Court’s Vermont Yankee decision in 1978.¹⁶ Nevertheless, while the prevailing judicial interpretation of the arbitrary-and-capricious standard of review (which became known as the “hard look doctrine”) has promoted reasoned decisionmaking, courts have not infrequently remanded rules on the basis of an agency’s failure to respond adequately to comments, consider relevant factors, or explain fully the bases for its rule. Courts should be sensitive not to require greater justification for rules than necessary; a reasoned statement that explains the basis and purpose of the rule and addresses significant issues raised in public comments should be adequate.

Pre-enforcement review, expanded by the Supreme Court in the 1967 *Abbott Laboratories* cases,¹⁷ endorsed by the Conference in various recommendations,¹⁸ and codified in numerous rulemaking programs, has the virtue of settling legal issues early and definitively. When overused, however, pre-enforcement review can have the negative effect of inducing precautionary challenges to most rules and the raising of as many objections to a rule as possible, including somewhat speculative challenges pertaining to the rule’s potential application.

Under the *Abbott Laboratories* standard, challenges to a rule are permitted where issues are appropriate for judicial review and where the impact on a challenger is direct and immediate. The Conference believes that the *Abbott Laboratories* standard strikes a sensible balance, and that pre-enforcement challenges generally are

appropriate where the administrative record provides a sufficient basis for the court to resolve the issue before it. Thus, a pre-enforcement challenge to a rule based on the procedures used in the rulemaking should normally be permitted. Pre-enforcement review that involves a facial challenge to a rule’s substantive validity (whether because of a conflict with a statute or the Constitution, or because of the inadequacy of the facts or reasoning on which it is based) should also generally be heard.¹⁹ In contrast, challenges to a rule because it might be applied in a particular way should normally be deferred until the rule has actually been applied.

Although prompt resolution of legal issues is to be encouraged, Congress should be cautious in coupling mandated time-limited pre-enforcement review with preclusion of review at the enforcement stage. Such time-limited review should be provided for only in the situations and conditions specified in Recommendation 82-7.²⁰ Where Congress does set time limits for pre-enforcement review, it should, in the interests of consistency, generally specify that pre-enforcement review should occur within 90 days of a rule’s issuance. Current statutory specifications vary. There does not seem to be any reason for variation that outweighs the benefits of uniformity in this context.

Congress should also amend any existing statutes that mandate use of the “substantial evidence” test for reviewing legislative rules, by replacing it with the “arbitrary and capricious” test. The occasional introduction of the substantial evidence test in the rulemaking context has created unnecessary confusion; some courts apply it in a manner identical to that of the “arbitrary and capricious” test; others believe that it sets a higher standard. The Conference believes that the arbitrary and capricious test provides sufficient review in the informal rulemaking context.

The intensity of judicial review directly affects the rulemaking process. For example, the scope of review of agency statutory interpretations is governed by the deferential *Chevron* test, which requires affirmance if the

¹⁰ 42 U.S.C. 7607.

¹¹ See Conference Recommendation 76-3, “Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking,” 1 CFR 305.76-3 (1993).

¹² See Conference Recommendation 78-3, “Time Limits on Agency Action,” 1 CFR 305.78-3 (1993).

¹³ See, e.g., Conference Recommendation 80-8, “Rulemaking and Policymaking in the Medicaid Program,” 1 CFR 305.80-8 (1993).

¹⁴ Where the “hammer” applied because of a failure to meet a deadline in that a proposed rule becomes effective, the anomalous result is that a policy that has withstood so public airing will be implemented.

¹⁵ Courts should continue, where appropriate, to consider whether agency action in a rulemaking is “unreasonably delayed.” See 5 U.S.C. 706(1); *Telecommunications Research and Action Center v. FCC*, 750 F.2d 78, 89 (D.C. Cir. 1984).

¹⁶ *Vermont Yankee Nuclear Power Corp. v. NRC*, 435 U.S. 519 (1978).

¹⁷ *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967); *Truitt v. Gentry*, 387 U.S. 138 (1967).

¹⁸ See Conference Recommendation 74-4, “Pre-enforcement Judicial Review of Rules of General Applicability,” 1 CFR 305.74-4 (1993); Conference Recommendation 91-4, “Facilitating the Use of Rulemaking by the National Labor Relations Board,” 1 CFR 305.91-4 (1993).

¹⁹ A challenge based on the facial invalidity of the rule, in this context, would normally be directed at a requirement or course of action to which the agency has clearly committed itself.

²⁰ Recommendation 82-7, “Judicial Review of Rules in Enforcement Proceedings,” 1 CFR 305.82-7 (1993), sets out criteria for when judicial review should be limited at the enforcement stage, and what kinds of issues should remain reviewable at that stage.

agency's interpretation of an ambiguous statute is permissible.²¹ On the other hand, when reviewing the reasonableness of an agency's policy and factual justifications for its rules, courts apply the stricter "hard look" doctrine.²² Deferential review of the legal issue of statutory interpretation, coupled with the rigorous review of a rule's factual and policy underpinnings that the "hard look" doctrine specifies, has been criticized as anomalous. The Conference believes, however, that the review standards can be harmonized by looking beyond the labels. That is, under both of these doctrines, courts are required to determine independently the limits of the agency's statutory authority and whether the factors the agency took into account in formulating the rule were permissible. Following that determination, courts properly defer to an agency's permissible reading of its statute and to its choice of inferences from the facts in making policy decisions. Courts would help make their review more consistent and predictable if they articulated more clearly this two-step approach. Both the *Chevron* and "hard look" doctrines would then be understood as including a searching review of the range of an agency's legally permissible choices (statutory, policy, and factual), combined with, in each instance, deference to the agency's reasonable selection among such choices, once the alternatives are determined to be within the permissible range.

Finally, in order to prevent additional litigation, courts should be encouraged to address certain issues that arise in many if not most reviews of rules. Reviewing courts should, for example, specify, to the extent feasible, which portions of the rule, if any, are to be set aside, vacated, stayed or otherwise affected by the decision in the case. They should seek to ensure that portions of a rule unaffected by a finding of illegality remain in effect, unless the rule expressly or impliedly indicates that the rule is inoperable. A reviewing court should also consider the extent to which its mandate will apply retroactively. In considering the effect to be given to its decision, the court should weigh the impact of the decision on parties not before the court, and recognize their interest in being heard or adequately represented prior to any ruling that adversely affects them.

Amendment of the APA

As we approach the fiftieth anniversary of the APA, some of its rulemaking provisions need to be updated. Section 553(c), which does not now state a length of time for the comment period, should be amended to specify that a comment period of "no fewer than least 30 days" be provided (although a good cause exception for shorter periods should be incorporated). This would relieve agencies of the need to justify comment periods that were 30 days or longer. The thirty-day period is intended as a minimum, not a maximum; agencies would still be encouraged to allow longer comment periods and to leave the record open for the receipt of late comments.²³ Section 553 should also specify that a second round of notice and comment is not required where the final rule is the "logical outgrowth" of the proposed rule, thus codifying generally accepted doctrine.²⁴ A provision requiring maintenance of a public rulemaking file should be incorporated into section 553, so that those who seek access to the file are not forced to rely on the Freedom of Information Act to obtain it.²⁵ (The content of such a file is discussed further below in connection with internal agency management initiatives.)

In addition, the requirement in section 553(c) of a statement of basis and purpose for the rule should be revised to require a "reasoned statement"²⁶ (deleting the "conciseness" provision), which includes a response to significant issues raised in the public comments.²⁷ These changes are designed to codify the salutary aspects of the caselaw on rulemaking, discourage insubstantial arguments and objections on review, and stem the tendency to require

additional, more burdensome justifications.

Another long-overdue change in the Act is elimination of section 553(a)(2)'s exemption from notice-and-comment procedures for matters relating to "public property, loans, grants, benefits, or contracts." As the Conference recognized as early as 1980, this "proprietary exemption" is an anachronism.²⁸ The exemption for "military or foreign affairs function[s]" in section 553(a)(1) should be narrowed so that all but secret aspects of those functions are open to public comment.²⁹

Internal Agency Management Initiatives

Rulemaking is not just a product of external constraints. The agency's own processes for developing rules and reviewing them internally affect the rulemaking environment. Thus, agency management initiatives can have a significant impact on the effectiveness and efficiency of rulemaking. The Conference recommends a number of steps agency managers can take to improve their internal processes.

Senior agency staff should develop management strategies to set priorities and track agency rulemaking initiatives.³⁰ Agencies should seek to involve the presidential oversight entity in the rulemaking process as early as feasible, in order to reach agreement on the significance of rules in the developmental stage, to provide greater coordination, and to speed final oversight review. Agencies should also review their existing systems for developing and reviewing regulations, to determine where problems and bottlenecks are occurring. They should seek to achieve more rapid internal clearances of proposed and final rules, and to develop reasoned analyses³¹ and responses to significant issues raised in public comments. They should also take steps to manage the rulemaking file (and associated requests for access to it).³²

²¹ See Conference Statement #7, "Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the Administrative Procedure Act," 1 CFR 310.7 (para. 3).

²² See *South Terminal Corp. v. EPA*, 804 F.2d 848, 859 (1st Cir. 1974), in which the 1st Circuit originated the "logical outgrowth" test. It was subsequently embraced by other circuits, particularly the D.C. Circuit. See *Shell Oil Co. v. EPA*, 650 F.2d 741 (D.C. Cir. 1981); *International Union, United Auto, Aerospace and Agr. Implement Workers of America v. OSHA*, 636 F.2d 1316 (D.C. Cir. 1981); *American Medical Association*, 887 F.2d 760 (7th Cir. 1988); *NRDC v. USEPA*, 824 F.2d 1258 (1st Cir. 1987); *United Steelworkers v. Schuykill Metal Corp.*, 839 F.2d 314 (8th Cir. 1987); *National Black Media Coalition v. FCC*, 791 F.2d 1016 (2nd Cir. 1986); *Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1008 (4th Cir. 1985).

²³ Statement #7, *supra* n. 21, at ¶4.

²⁴ *State Farm*, *supra* n. 22, 463 U.S. at 57 (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970)).

²⁵ Conference Statement #7, *supra* n. 21, at ¶5.

²⁶ See Conference Recommendation 66-8, "Elimination of Certain Exemptions From the APA Rulemaking Requirements," 1 CFR 305.66-8 (1993).

²⁷ See Conference Recommendation 73-4, "Elimination of the 'Military or Foreign Affairs Function' Exemption from APA Rulemaking Requirements," 1 CFR 305.73-4 (1993).

²⁸ See Conference Recommendation 87-1, "Priority Setting and Management of Rulemaking by the Occupational Safety and Health Administration," 1 CFR 305.87-1 (1993).

²⁹ See Conference Recommendation 86-2, "Agency Procedures for Performing Regulatory Analysis of Rules," 1 CFR 305.86-2 (1993); Conference Recommendation 86-7, "Valuation of Human Life in Regulatory Decisionmaking," 1 CFR 305.86-7 (1993).

³⁰ Computerized access should be made available, preferably in a uniform system government-wide. See Conference Recommendation 86-10, "Federal Agency Use of Computers in Acquiring and Releasing Information," 1 CFR 305.86-10 (1993).

²¹ *Chevron USA Inc. v. NRDC*, 467 U.S. 837 (1984).

²² *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983) (*State Farm*).

Agencies should also consider innovative methods for developing and getting public input on rules. Agencies should use advisory or negotiated rulemaking committees where appropriate to improve the quality and acceptability of rules.³⁴ They should also consider the use of "direct final" rulemaking where appropriate to eliminate double review of noncontroversial rules. Direct final rulemaking involves issuing a rule for notice and comment, with an accompanying explanation that if the agency receives no notice during the comment period that any person intends to file an adverse comment, the rule will become effective 30 days (or some longer period) after the comment period closes.

Recommendation

To improve the environment for agency legislative rulemaking, the President, Congress, and the courts should take steps to eliminate undue burdens on agency legislative rulemaking: Congress should update the Administrative Procedure Act's rulemaking provisions; and agencies should review their internal rulemaking environment and, where appropriate, implement internal management initiatives aimed at improving the effectiveness and efficiency of their efforts.

I. Presidential Oversight³⁵ of Rulemaking

A. The President's program for coordination and review of agency rules should be set forth in a directive that is reviewed periodically. The program should be sensitive to the burdens being imposed on the rulemaking process, and implementation of the program should ensure that it does not unduly delay or constrain rulemaking. The President should consider the cumulative impact of existing analytical requirements on the rulemaking process before continuing these requirements or imposing new ones.³⁶

B. The President's directive, as well as the explanations provided and the procedures followed by the presidential oversight entity, should, insofar as practicable:

1. Promote dialogue and coordination between the oversight entity and rulemaking agencies in the early identification and selection of rules warranting application of the review process;
2. Set forth the relevant analytical requirements that the oversight entity should apply to agency rulemaking, and provide interpretive guidance to assist agencies in complying with these requirements;
3. Ensure appropriate expedition and openness in the process, in accordance with Conference Recommendation 88-0;
4. Support a process for planning regulatory initiatives and tracking rule development; and
5. Encourage and support agency efforts to use consensual processes such as negotiated rulemaking.

II. Congressional Structuring of Rulemaking

A. Section 553 of title 5, United States Code, which established the framework for legislative rulemaking, has operated most efficiently when not encumbered by additional procedural requirements. Congress generally should refrain from creating program-specific rulemaking procedures or analytical requirements beyond those required by the APA. When Congress determines that additional procedures beyond those required by section 553 are justified by the nature of a particular program, such procedures should be focused on identified problems and, where possible, adopted incrementally or after experimentation.³⁷ In addition, Congress should repeal formal ("on-the-record") or other adjudicative fact-finding procedures in rulemaking in any existing statutes mandating such procedures.³⁸

we express no position on the substantive policies being mandated.

³⁷ See, for example, the development of more specific, but not necessarily more burdensome, procedures for EPA rulemaking that has significant economic and competitive effects. See 42 U.S.C. § 7607 (5307 of the Clean Air Act). See also Conference Recommendation 78-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking," 1 CFR 306.78-3 (1983), which encourages agency experimentation with use of oral procedures beyond simple notice and comment in some circumstances.

³⁸ Conference has recommended against the mandated use of cross-examination and other "adjudicative" procedures for agency fact-finding in rulemaking. See, e.g., Conference Recommendation 78-1, "Hybrid Rulemaking Procedures of the Federal Trade Commission," 1 CFR 306.78-1 (1983). The Conference recognizes, however, that

B. In general, Congress should not legislate time limits on rulemaking, but should instead rely on judicial enforcement of prompt agency action under § 706(1) of the APA.³⁹ However, if Congress determines that a deadline is appropriate, it also should ensure that the agency has sufficient resources to support the required rulemaking effort without distorting the agency's other regulatory functions. If Congress further determines that a default rule is necessary where an agency does not meet a deadline, it should specify the terms of that rule and, in particular, should not impose "regulatory hammers" that would cause the agency's proposed rules to take effect automatically.

C. Congress should reconsider the need for continuing statutory analytical requirements that necessitate broadly applicable analyses or action to address narrowly-focused issues.⁴⁰ If Congress nonetheless determines that such analytical requirements are necessary, Congress should structure its requirements more narrowly (e.g., by confining their application to the most significant rules or to rules likely to be affected by the stated concern).

III. Timing and Scope of Judicial Review

Congress and the courts generally should be sensitive to the impact of judicial review on agency rulemaking and should seek to simplify, clarify, and harmonize provisions for judicial review of rules.

A. Congress and the Courts

In determining whether pre-enforcement challenges to rules are appropriate, courts have traditionally evaluated "both the fitness of the issues for judicial decision and the hardship to the parties of withholding its consideration."⁴¹ Adherence to this standard benefits both agencies and those affected by agency rules. Congress

more formal procedures may be appropriate for rulemaking based on party-related facts. See *United States v. Florida East Coast R.R.*, 410 U.S. 224 (1973). Congress may also wish to consider whether less formal hybrid processes may be useful in contexts currently requiring formal rulemaking.

³⁹ This is not a comment on the legitimacy of congressional directives in this regard, but on their impracticality. On the other hand, agency self-imposed deadlines are encouraged, see VTD, below. For more detailed advice on time limits, see paragraph 5 of Conference Recommendation 78-3, "Time Limits on Agency Action," 1 CFR 306.78-3 (1983).

⁴⁰ See, e.g., the Regulatory Flexibility Act of 1980. The Conference takes no position on the substantive issues the Act seeks to address. Insofar as possible, however, such concerns are more appropriately included in the President's oversight guidelines. See I(B)(2) above.

⁴¹ *Abbott Laboratories v. Gardner*, supra n. 17, 387 U.S. at 149.

³³ "Written" includes documents in electronic form.

³⁴ Any government-wide policy concerning the use of advisory committees should be consistent with their use as part of the process of negotiated rulemaking.

³⁵ The recommendations contained in this section apply to oversight of both executive and independent agencies. The Conference has previously recommended that presidential review of rulemaking apply to the independent agencies to the same extent it applies to the rulemaking of the Executive Branch departments and agencies. See Conference Recommendation 88-0, "Presidential Review of Agency Rulemaking," 1 CFR 305.88-0 (1983).

The term "presidential oversight entity," as used herein, is that part of the Executive Office of the

generally should authorize and courts should allow preenforcement challenges where the administrative record is a sufficient basis for resolving the issues. Thus, preenforcement challenges to a rule based on the procedures used in the rulemaking or on the asserted substantive invalidity of the rule, however it would be applied, should normally be permitted. Claims of substantive invalidity would include facial challenges based on statutory or constitutional grounds, or asserting the inadequacy of the facts or reasoning underlying the rule. Challenges to a rule on the basis that the rule might be applied in a particular way should normally be deferred until the application seems likely or has occurred.

B. Congress

1. Congress should be cautious in mandating time-limited preenforcement review coupled with preclusion of review at the enforcement stage, and should rely on time limits only in the situations and conditions specified in Recommendation 82-7.⁴² Congressional time limits on preenforcement review should be understood to bar later challenges in the enforcement context only to the extent specified by Congress. Where Congress mandates a time limit on preenforcement review, it generally should specify that such review be requested within 90 days of the issuance of the rule.⁴³ It should also provide that preenforcement review cases be directly reviewable in the courts of appeals, and that a stay or partial stay of the rule's effectiveness ordinarily be issued only on the demonstration of likelihood of success on the merits and the prospect of significant private harm if the rule is permitted to take effect.

2. The standards set out in § 706(2)(A) of the APA's judicial review provisions should apply in all cases involving review of rules. Specifically, Congress should not provide for the use of the "substantial evidence" test for agency rules. It should conform existing statutes to this standard by deleting the use of the "substantial evidence" test for review of agency rules.

C. Courts

1. In articulating the doctrines used in the judicial review of rulemaking, reviewing courts should more clearly harmonize the deferential *Chevron* doctrine, applied in reviewing agency interpretation of its statutory authority,

with the "hard look" doctrine, used in examining an agency's justification for its rule. Courts, in applying these doctrines, should recognize that both the *Chevron* and "hard look" tests call for a searching review of the range of factors or permissible choices that may be considered by the agency, and require deference to agency application of those factors once they are shown to be legally appropriate.

2. When reviewing an agency's explanation for its rule, courts should consider the context of the entire proceeding and concern themselves principally with whether the agency's overall explanation and analysis is reasonable, including its response to the significant issues raised in public comments.

3. In reviewing challenges to agency rules, courts should, to the extent feasible and after taking into account the effect of the decision on affected persons not before the court, consider: (a) Whether any portion of a rule unaffected by a finding of illegality should remain in full force and effect; (b) which portions of the challenged rule, if any, are to be set aside, vacated, stayed, or otherwise affected by the court's decision in a case; and (c) the extent to which the court's mandate should apply retroactively.

4. Courts should continue, where appropriate, to consider whether agency action in a rulemaking is "unreasonably delayed."⁴⁴

IV. Amendments to the APA's Legislative Rulemaking Provisions

Congress should update the APA and eliminate outmoded provisions. It should codify court decisions that have increased the effectiveness of public participation in the rulemaking process. In particular, Congress should consider amending section 553 of the APA to:

A. Eliminate the exemption (§ 553(a)(2)) for rules relating to public property, loans, grants, benefits or contracts, and delete the exemption (§ 553(a)(1)) of military and foreign affairs matters, except for secret matters;⁴⁵

⁴² See e.g., 15, 30, *supra*.

⁴³ See Conference Recommendation 66-4.

"Elimination of Certain Exemptions From the APA Rulemaking Requirements," 1 CFR 205.60-6 (1993), and Conference Recommendation 73-5.

"Elimination of the Military or Foreign Affairs Function Exemption from APA Rulemaking Requirements," 1 CFR 205.73-5 (1993). The latter recommendation urged eliminating the APA's categorical exemption for matters pertaining to the military or foreign affairs function. It does recognize, however, that a modified exemption may be appropriate for matters "specifically required by executive order to be kept secret in the interest of national defense or foreign policy."

B. Specify a comment period of "no fewer than 30 days" (§ 553(c)).⁴⁶ provided that a good cause provision allowing shorter comment periods or no comment period is incorporated, and codify the doctrine holding that a second round of notice and comment is not required if the final rule is a "logical outgrowth" of the noticed proposed rule;

C. Require establishment of a public rulemaking file beginning no later than the date on which an agency publishes an advance notice of proposed rulemaking or notice of proposed rulemaking, whichever is earlier.

D. Restate the "concise" statement of basis and purpose requirement (§ 553(c)) by codifying existing doctrine that a rule must be supported by a "reasoned statement," and that such statement respond to the significant issues raised in public comments.

To the extent permitted by law, agencies should adopt these proposed policies pending Congressional action.

V. Agency Management Initiatives

In order to improve their internal rulemaking environments, agencies should develop management techniques to ensure efficient and effective administration of rulemaking. Such techniques should include:

A. Systematically setting priorities at the highest agency levels and tracking rulemaking initiatives, including identifying clearly who has the authority to ensure that agency schedules and policies are followed;

B. Coordinating with the presidential oversight entity on the identification of rules warranting review as early in the process as is feasible, and establishing internal review procedures at the highest levels to ensure compliance with presidential analytical requirements;

C. Reviewing the agency's existing system for developing and reviewing regulations, to determine where problems and bottlenecks are occurring, and to improve and streamline the process;

D. Achieving timely internal clearances of proposed and final rules, using, where feasible, publicly announced schedules for particular rulemaking proceedings;

E. Managing rulemaking files, so that maximum disclosure to the public is achieved during the comment period and so that a usable and reliable file is available for purposes of judicial review. The rulemaking file should,

⁴⁶ The 30-day period is intended as a minimum, not a maximum. Agencies are encouraged to use longer periods for public comment.

⁴⁴ See Conference Recommendation 82-7, "Judicial Review of Rules in Enforcement Proceedings," 1 CFR 205.63-7 (1993).

⁴⁵ Congress should likewise reevaluate existing statutes for conformity with this approach.

insofar as feasible, include (1) all notices pertaining to the rulemaking, (2) copies or an index of all written⁴⁷ factual material, studies, and reports substantially relied on or seriously considered by agency personnel in formulating the proposed or final rule (except insofar as disclosure is prohibited by law), (3) all written comments submitted to the agency, and (4) any other material required by statute, executive order, or agency rule to be made public in connection with the rulemaking.⁴⁸

F. Making use, where appropriate, of negotiated rulemaking and advisory committees;

G. Considering innovative methods for reducing the time required to develop final rules without eliminating the opportunity for consideration and comment;

H. Taking steps to ensure that proposed rules are acted on in a reasonably timely manner or withdrawn; and

I. Evaluating and reconsidering existing rules and initiating amendments and repeals where appropriate.

Recommendation 93-5 Procedures for Regulation of Pesticides.

The Environmental Protection Agency cannot accomplish its substantive mission in regulating pesticides without change and improvement in the Agency's regulatory procedures. The Conference recommends the adoption of a more coordinated and strategic procedural framework for the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). EPA needs procedures that create multiple and reinforcing incentives for regulatory compliance by registrants, for timely and accurate decisionmaking by EPA, and for effective public participation.

The Reregistration Process

The reregistration of existing pesticides under contemporary risk assessment standards, and the removal of unacceptable pesticides from the marketplace, are examples where procedures can hinder the agency's prospects for success in its substantive mission. Reregistration of existing pesticides, which Congress originally directed to be completed by 1976, became sufficiently delayed so that Congress in 1988 amended FIFRA

specifically to force the completion of reregistration by 1998. Yet subsequent delays in the reregistration process may cause EPA to miss this congressional deadline. To some extent, the delay may reflect the underlying difficulty and resource-intensiveness of the risk assessment enterprise with which EPA has been charged. There are some 50,000 pesticide products that are separately formulated from 642 identified active ingredients. Although EPA has tried to expedite its task by focusing reregistration on some 402 "cases" (composed of single or related active ingredients), each case can require evaluation of 100-150 separate studies, every one of which may pose further questions of scientific protocol and interpretation. It may be that EPA's Office of Pesticide Programs needs more personnel to match its regulatory task.

Whatever the case for additional resources (a question not addressed by the Conference), there is a more basic need for timely and adequate data from registrants—all else in the reregistration process depends on this. Yet the reregistration process does not now provide sufficient procedural incentives to encourage submission of timely and adequate data. In general, because registrants continue to market their products during reregistration, they have little to lose by regulatory decisions that are reached later rather than sooner. Although the 1988 FIFRA Amendments require registrants to identify data gaps, and commit to fill them, the 1988 Amendments do not provide the agency with sufficient tools to police tardy or inadequate data submissions.

As to tardiness, the 1988 Amendments authorized the agency to suspend registrations of those registrants that fail to submit data. But EPA must first provide nonsubmitters with 30-days' notice in response to which registrants can demand a limited hearing (which must be held within 75 days); the 1988 Amendments further provide that registrants suspended for not submitting data can have their registrations "reinstated" upon submission of the data. Some registrants, ironically, have used these suspension procedures as a means of obtaining penalty-free and self-awarded extensions of time. In the 7 months between August 1991 and February 1992, for example, EPA found it necessary to issue 70 Notices of Intent to Suspend for nonsubmittal of data, yet in the majority of these instances (53) the registrants merely submitted their data prior to exhausting their procedural rights and were no worse off for having missed their deadlines. To create an

additional disincentive for untimely data submissions it is necessary to make lateness costly to the registrant. To this end, the Conference recommends that Congress authorize EPA to impose civil money penalties for untimely data.

As to the adequacy of data, EPA may now have the theoretical (but untested in court) capacity to suspend or cancel the registration of those pesticides for which inadequate data have been submitted. However, the more common response to inadequate data is a "data call-in," through which the agency demands that studies be redone—a source of additional delay that the agency has identified as significant. Even with respect to its highest priority pesticides, EPA has in the recent past found 50 percent of studies to be either inadequate, "upgradable" or otherwise requiring supplementation. Although the cost of redoing studies should provide some incentive for registrants to ensure that their studies meet EPA's quality criteria, it does not seem to provide a sufficient incentive. In fairness to some registrants, there is evidence that EPA itself may be partially to blame for the high rates of data rejection. In 1992, an internal agency review found that misinterpretation of data requirements and poor guidance from EPA case managers were in part responsible for the inadequacy of data submissions. The Conference therefore recommends that EPA promulgate and communicate clear data standards and guidance on the data expected from registrants. To help prevent the submission of inadequate data even after sufficiently clear agency guidance has been given, the Conference recommends that Congress authorize EPA to levy administrative civil money penalties upon registrants submitting data that fail to meet previously announced standards. This will not only create incentives for registrants to take the extra steps necessary to ensure the adequacy of their submittals, but it will also create incentives for the agency to make clear its expectations.

Whatever the additional tactical advantages that the agency may gain by improving its own ability to enforce data timeliness and adequacy, the sheer number of studies and the innumerable decisions requiring agency discretion suggest that more global incentives are needed to ensure that registrants themselves have a stake in timely and adequate data. The danger is that the reregistration process now has become, even with the best of intentions, an analytical treadmill powered by the rhythms of data call-ins, subsequent requests for data waivers and time extensions, submission of data that do

⁴⁷ "Written" includes documents in electronic form.

⁴⁸ See Conference Statement #7, 1 CFR 310.7 (1993). "Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the Administrative Procedure Act."

not always meet EPA's standards for adequacy, and further data call-ins that restart the sequence. The Conference believes that the unique demands of the reregistration process justify congressional consideration of a "hammer" provision that would legislatively impose an automatic suspension of all "List A" pesticides (those high-priority pesticides to which there is greatest human exposure) for which there are still significant data gaps within the registrant's control, and of which the registrant is aware—subject to a provision for a registrant to petition for reinstatement. Such a provision would not only provide an overarching incentive for registrants to favor the completion rather than postponement of their data obligations, but it would also better align the reregistration process with FIFRA's central procedural presumption—that, in the face of uncertainty, applicants (especially those seeking to reregister pesticides with extensive human exposure) should bear the burden of proof in establishing that their pesticides do not pose unreasonable risks.

Suspension and Cancellation Hearings

Apart from improvements in the reregistration process, the Conference urges Congress to substitute a relatively informal decisionmaking process for the formal adjudicatory hearings that registrants can now demand in cancellation and suspension matters. In the past, formal hearings under FIFRA have averaged 1,000 days to complete. These hearings can directly impose on EPA significant resource costs and can also indirectly discourage the agency from aggressive prehearing negotiations with registrants (lest the registrant "take EPA to hearing"). It is not surprising that EPA has long sought alternatives to cancellation hearings. For years, it sought to identify problem pesticides for heightened regulatory attention in a "Special Review" process. There is little need for procedural formality in these types of decisions. At issue in most cancellation and suspension proceedings are scientific data concerning risks and benefits, disputes over which can generally be well-ventilated when EPA gives registrants detailed reasons for the agency's actions and then provides registrants with sufficient time to file responsive written comments and supporting documentation. For those cases where oral testimony or cross-examination is justified, the benefits of more formal procedures can be preserved by providing registrants an opportunity to show cause why such procedures are warranted. Accordingly, the Conference

recommends that Congress pattern cancellation and suspension proceedings on a basic notice-and-comment model, with more formal procedures available only if a party will be demonstrably prejudiced by the informal procedure.

Labeling and Phase-down Procedures

Although the reregistration process and adjudicatory hearings are the most visible aspects of pesticide regulation in need of procedural improvement, they are not the only places where procedural reform is important. Since the late 1980's, EPA has in fact sought to reduce the risks of pesticides through private negotiations with registrants over label changes that impose restrictions on use. Such regulatory action has the potential to attain interim risk-reduction quickly when warranted by available data, without going through the cumbersome Special Review and cancellation procedures, even when complete reregistration may still be years away. But there are also disadvantages to relying so heavily on private negotiations with registrants—chief among them the lack of participation among the various interested publics in crafting label changes. In the early 1980's, similar concern about privately negotiated Special Review and pre-Special-Review decisions seriously undermined the agency's credibility and slowed regulatory progress. In 1985, EPA adopted procedures to open the door for information from, and participation by, the public in those processes.¹ The Conference recommends that EPA adopt analogous procedures to regularize and open the agency's negotiated label program. In addition, because label changes are effective in reducing risk only if they are actually implemented in the field, the Conference recommends procedures to facilitate feedback from registrants, pesticide users, and all other interested persons on the effectiveness or ineffectiveness of the interim risk-reduction measures EPA has adopted. Moreover, the Conference recommends that EPA's Office Of Pesticide Programs (OPP) establish regular channels of communication with EPA's Office of Enforcement and Compliance Assurance to inform that office of all label changes and of any material information received by OPP on noncompliance with such changes.

The Conference also urges Congress to consider providing EPA with a new procedural device designed to accommodate a safer pesticides policy: The ability by informal procedures to

order the phase-down of existing pesticides when there are available for use safer, effective pest management products or practices.² Empowering the agency to develop an informal phase-down mechanism would have several procedural advantages. First, ordering the phase down of an existing pesticide on relative risk grounds will cause less stigmatization of an existing product than would a cancellation proceeding based on the traditional, more absolutist "unreasonable risk" judgment. Second, phase-down procedures provide for an incremental style of decisionmaking in which EPA's reasoned judgments about comparative risk can be tested and reevaluated without making irreversible decisions about existing pesticides in cancellation proceedings. Finally, phase-down procedures based on relative risk can reinforce and integrate EPA's pesticide programs under FIFRA with other federal environmental programs.

Recommendation

I. Adequacy and Timeliness of Data

A. EPA should adopt, whenever possible, rules setting clear standards for pesticide reregistration data and should communicate those standards to registrants.

B. Congress should authorize EPA to impose administrative civil money penalties on registrants for the failure to submit data by any applicable deadline, or for submitting data (even if timely) that do not comply with the data standards adopted by EPA.³

C. Congress should consider imposing an automatic suspension of "List A" (high priority) pesticides for which there still remain, by a date to be set by Congress, previously identified and significant gaps in data within the registrant's control, and of which the registrant is on notice. Once suspended, pesticides could be reinstated through a petition process.

II. Informal Procedures

A. Congress should eliminate the provisions in FIFRA allowing for formal adjudicatory hearings in proposed suspension or cancellation actions and should provide instead an informal procedure, including notice in the

¹ Without taking any position on the substantive questions involved in determining the relative safety and effectiveness of pest control measures, the Conference notes EPA's interest in both the present and prior presidential administrations in developing such a substantive capability.

² Imposition of penalties should be through formal adjudication. See Conference Recommendation 50-1 "Use of APA Formal Procedures in Civil Money Penalty Proceedings," 59 FR 45408 (Aug. 30, 1994).

³ 40 CFR Part 154, Subpart B.

Federal Register, that informs registrants and others of the specific grounds on which EPA bases its proposed action and that provides a reasonable opportunity to file written comments and data. Only if a party will be demonstrably prejudiced by the written notice-and-comment process should the agency be required to grant the right to introduce oral testimony or to subpoena and cross-examine witnesses.

B. Congress should consider providing EPA the authority to order a phase down in the use of any registered pesticide through an informal notice-and-comment procedure in which EPA considers such factors as the relative risks and benefits of the pesticide at issue when compared with alternative pest management products and practices.

III. Public Participation

A. EPA should regularize and open for broader public participation its informal procedures for achieving interim risk reduction through pesticide label changes. EPA should inform the public, through a Federal Register notice, when it commences private label negotiations with registrants. EPA should simultaneously open a public "negotiation docket" into which interested persons may submit comments they believe might be relevant, for consideration by EPA and the registrants during their negotiations. If, after negotiations with registrants, EPA proposes a label change, it should publish a notice of the proposed change in the Federal Register and provide the public an opportunity to file written comments. The notice should include a concise, general statement of the proposed label's basis and purpose, including a summary of the material aspects of the agency's negotiations with registrants.

B. After requiring a label change, EPA should establish and publicize the availability of a "compliance docket," for any input about the effectiveness or ineffectiveness of interim risk-reduction measures. In addition, EPA's Office of Pesticide Programs (OPP) should communicate to EPA's Office of Enforcement and Compliance Assurance the adoption by OPP of label changes and any material information received by OPP in its compliance docket.

STATEMENT OF THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

The following formal statement was adopted by the Assembly of the Administrative Conference on December 9, 1993:

Statement No. 18 Right to Counsel With Counsel in Agency Investigations

In recent years, Congress has attached sanctions to an increasingly wide range of regulatory violations, causing federal administrative agencies to become involved more routinely in investigations that lead to civil or criminal prosecution. The Administrative Conference has completed a study that explores the procedures that govern the relationship between the agency and a person compelled to appear before the agency in such investigations.

The Administrative Procedure Act in section 555(b) provides that "[a] person compelled to appear in person before an agency or representative thereof is entitled to be accompanied, represented, and advised by counsel or, if permitted by the agency, by other qualified representative. A party is entitled to appear in person or by or with counsel or other duly qualified representative in an agency proceeding." This brief reference to counsel in the APA leaves a number of questions open. The Act, for example, does not specify the types of actions attorneys may take in representing their clients during agency investigative proceedings. It also does not indicate precisely which persons coming in contact with an agency may invoke the right to counsel.¹

Because the roles of investigators in federal agencies, and the methods by which witnesses or parties appear before agencies vary considerably, the Administrative Conference does not believe it can develop a uniform set of recommendations concerning these procedures. However, the Conference believes it would be valuable to provide a statement on some of the issues raised in such investigations concerning the role of counsel so that those government officials involved can be made aware of the issues and seek additional guidance where warranted.

I. Agency Exclusion of Counsel

Although courts construing the APA's right-to-counsel provision have held that the right includes the power to

retain counsel of one's own choosing, some federal agencies have, by rule or order, reserved the power to exclude counsel who represents a person compelled to appear before an agency representative during an investigation. They have done so out of a concern that the particular attorney may impair the effectiveness of the investigation, especially where the attorney represents either multiple witnesses, or a witness and his or her employer.

Agencies should consider whether, in most situations, a person compelled to appear in agency investigative proceedings ought to have the discretion to choose his or her own counsel, even where counsel represents multiple witnesses or parties in the matter. As courts have held, an agency must have "concrete evidence" that an investigation will be impaired before it may exclude counsel.² Thus, the mere fact of multiple representation, an employment relationship between the witness and some other party involved in the investigation, or past dealings between the agency and a particular attorney should not be considered, in and of themselves, a sufficient basis for excluding the counsel of a witness.

Regardless of an agency's decision on the above matter, it has the power to exclude counsel for disruptive or obstructive behavior during the proceedings, and to take action in situations where the attorney is suspected of personal involvement in the potential violations or actions under investigation.

II. Consultation With Auxiliary Experts

Because of the highly technical nature of many regulatory fields, attorneys who advise witnesses or parties in some agency investigations must consult with accountants, engineers, economists, or other experts in order to provide effective legal assistance. The prevailing practice among federal agencies is to allow such consultation with auxiliary personnel, either by allowing the expert to attend the proceedings or by allowing the attorney a reasonable opportunity during the proceeding to consult with the expert about the substance of the investigation. Agencies that do not currently provide this opportunity should consider whether to allow counsel representing a person compelled to appear before the agency reasonable access to auxiliary experts, regardless of whether the investigation involves civil or criminal sanctions.

¹ See *SEC v. Cough*, 283 F.2d 7 (D.C. Cir. 1957); *Professional Reactor Operator Society v. NRC*, 938 F.2d 1047 (D.C. Cir. 1991).

² The 1994 Attorney General's Report on Administrative Procedure in Government Agencies is strongly critical on the subject of legal representation. See, Doc. No. 4, 77th Cong., 1st Sess. (1991). The report throughout refers to the presentations and conversations of "parties," without any indication whether parties would or would not have the benefit of legal counsel. Statements in both House and Senate committee reports regarding this provision of the APA state simply that it is "designed to confer and make effective" the "statutory and mandatory right" of interested persons to appear personally or with counsel before the agency. See, Doc. No. 248, 78th Cong., 2d Sess. 205, 283 (1946).

III. Informing Persons of Their Right to Counsel

Agencies should be sensitive to the right to counsel that persons compelled to appear before it are granted under the APA and other statutes, and should consider when it is appropriate to advise such an individual of this right. Where necessary, agencies should consider providing training on this subject to field investigators. In the interest of maintaining an effective working relationship between federal regulatory agencies and regulated parties, agencies should consider whether it is appropriate to conduct a compelled investigative proceeding in the absence of legal counsel when it is apparent that a person is unaware of his or her right to counsel.

[FR Doc. 94-2225 Filed 1-31-94; 8:45 am]
BILLING CODE 0110-01-W

DEPARTMENT OF AGRICULTURE

Cooperative State Research Service

National Agriculture Research and Extension Users Advisory Board and Joint Council on Food and Agricultural Sciences; Meeting

According to the Federal Advisory Committee Act of October 6, 1972 (Public Law 92-463, 86 Stat. 770-776), as amended, the Office of Grants and Program Systems, Cooperative State Research Service, announces the following meeting:

Name: National Agricultural Research and Extension Users Advisory Board and the Joint Council on Food and Agricultural Sciences.

Date: February 13-16, 1994.

Time: February 13-3:30 p.m.-6 p.m. (UAB). February 14-8:30 a.m.-5:30 p.m. (UAB & JC). February 15-8:30 a.m.-5:30 p.m. (UAB & JC). February 16-8:30 a.m.-5:30 p.m. (UAB).

Place: U.S. Department of Agriculture, 14th & Independence Avenue, SW., Administration Building, room 104A, Washington, DC 20250.

Type of meeting: Open to the public. Persons may participate in the meeting as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person named below.

Purpose: To review FY95 proposed budget for agricultural science and education programs and write FY96 priorities report.

Contact person for agenda and more information: Ms. Marshall Turkington, Executive Director, Science and Education Advisory Committee; room 316-A, Administration Building, U.S. Department of Agriculture, Washington, DC 20250; Telephone (202) 720-3684.

Done in Washington, DC, this 23rd day of January 1994.

John Patrick Jordan,
Administrator.

[FR Doc. 94-2201 Filed 1-31-94; 8:45 am]
BILLING CODE 3410-02-0

Federal Grain Inspection Service

Designation of the State of Alabama

AGENCY: Federal Grain Inspection Service (FGIS).

ACTION: Notice.

SUMMARY: FGIS announces the designation of Alabama Department of Agriculture and Industries (Alabama) to provide official inspection and Class X or Class Y weighing services under the United States Grain Standards Act, as amended (Act).

EFFECTIVE DATE: March 1, 1994.

ADDRESSES: Neil E. Porter, Director, Compliance Division, FGIS, USDA, Room 1647 South Building, P.O. Box 96454, Washington, DC 20090-6454.

FOR FURTHER INFORMATION CONTACT: Neil E. Porter, telephone 202-720-8262.

SUPPLEMENTARY INFORMATION:

This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866 and Departmental Regulation 1512-1; therefore, the Executive Order and Departmental Regulation do not apply to this action.

In the September 1, 1993, Federal Register (58 FR 46158), FGIS announced that the designation of Alabama ends on February 28, 1994, and asked persons interested in providing official services within the specified geographic areas to submit an application for designation. Applications were due by October 1, 1993. Alabama, the sole applicant, applied for designation in the entire area currently assigned to it.

FGIS requested comments on the applicant in the October 29, 1993, Federal Register (58 FR 58148). Comments were due by December 1, 1993. FGIS received no comments by the deadline. FGIS evaluated all available information regarding the designation criteria in Section 7(f)(1)(A) of the Act; and according to Section 7(f)(1)(B), determined that Alabama is able to provide official services in the geographic area for which they applied.

Effective March 1, 1994, and ending February 28, 1997, Alabama is designated to provide official inspection and Class X or Class Y weighing services in the entire State of Alabama, except those export port locations within the State.

Interested persons may obtain official services by contacting Alabama at 205-690-6154.

AUTHORITY: Pub. L. 94-462, 90 Stat. 2867, as amended (7 U.S.C. 71 et seq.)

Dated: January 26, 1994

Neil E. Porter

Director, Compliance Division

[FR Doc. 94-2126 Filed 1-31-94; 8:45 am]

BILLING CODE 3410-02-0

Request for Applications from Persons Interested in Designation to Provide Official Services in the Geographic Area Presently Assigned to the Jamestown (ND) Agency

AGENCY: Federal Grain Inspection Service (FGIS).

ACTION: Notice.

SUMMARY: The United States Grain Standards Act, as amended (Act), provides that official agency designations shall end not later than triennially and may be renewed. The designation of Grain Inspection, Inc. (Jamestown), will end July 31, 1994, according to the Act, and FGIS is asking persons interested in providing official services in the specified geographic area to submit an application for designation.

DATES: Applications must be postmarked or sent by telecopier (FAX) on or before March 2, 1994.

ADDRESSES: Applications must be submitted to Neil E. Porter, Director, Compliance Division, FGIS, USDA, Room 1647 South Building, P.O. Box 96454, Washington, DC 20090-6454. Telecopier (FAX) users may send applications to the automatic telecopier machines at 202-720-1015, attention: Neil E. Porter. If an application is submitted by telecopier, FGIS reserves the right to request an original application. All applications will be made available for public inspection during regular business hours at this address located at 1400 Independence Avenue, S.W.

FOR FURTHER INFORMATION CONTACT: Neil E. Porter, telephone 202-720-8262.

SUPPLEMENTARY INFORMATION:

This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866 and Departmental Regulation 1512-1; therefore, the Executive Order and Departmental Regulation do not apply to this action.

Section 7(f)(1) of the Act authorizes FGIS' Administrator to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better

Dr. GOLDMAN. And also, we have copies for you.

Mr. STENHOLM. I have had numerous conversations with the other committees of jurisdiction, Chairman Waxman, of the Subcommittee on Health and Environment, of the Energy and Commerce Committee, and made it very clear that this committee will not mark up a FIFRA bill only, and then depend upon the good judgment of another committee to put together a package that will in fact serve the needs of consumers and production agriculture.

I think that is irresponsible. And so, therefore, we hope that as we proceed, and I expect this to be the case, that we will be able to proceed in recognizing that this must be in a package.

If we can't put together a package that deals with the total needs, it is going to be impossible to deal with the parts. And I, in my conversation with Mr. Waxman, made it very clear that I intend to mark up in his jurisdiction, and I expect him to mark up in ours. That doesn't bug me like it bugs some people. And, in fact, the sooner we get on with that kind of legislating, the better off we all will be.

So I hope that as we continue to proceed, even though you did send two bills for the reason which you explained, that we can proceed from the standpoint of recognizing that we must move together in tandem or we will make some very serious mistakes as regards to production agriculture and will have a very detrimental effect to consumers in this country.

One question regarding the chart of the comparison between the two, one area you showed in which there was a difference, expanded recordkeeping, yes, in your bill, and none in H.R. 1627. Why, in your judgment, do only farmers have to keep records for general-use pesticides?

Why not the households, gardener or the pool guard who is using general-use chemicals should keep records also?

Dr. GOLDMAN. Actually, we do not believe that farmers only should keep records. What our proposal involves is that there be recordkeeping by agricultural users and commercial applicators. For the agricultural users, we believe this is necessary because they are applying potentially dangerous chemicals on food.

For commercial applicators, we believe that they should be required to keep records because there is in the relationship of hiring a commercial applicator that you have somebody who can use a restricted-use pesticide. They are in the business of applying pesticides, and we believe that for both the consumers and for the enforcement side, that we should be able to access records about which pesticides they applied.

Mr. STENHOLM. You are not concerned about general use?

I don't argue with that. I mean, no one can quarrel with the rationale of that answer.

Dr. GOLDMAN. We are concerned about general use, but we believe that the appropriate way to deal with the use by the consumers is through the information that is on the pesticide label that is provided for them. And we believe also that the consumers should know which pesticide they applied in their own home.

One of the things that we have experienced is that we have seen cases in our enforcement program where commercial applicators have applied a pesticide in an office building improperly, and then

people, workers in that building, have become ill. And then when the EPA or the State have gone out to do the investigation of what happened, the commercial applicator has said that they don't know which pesticide was applied.

We think that this is an unacceptable situation. We think that a commercial applicator should be required to have a record so that if a business suffers damage of that sort, that we would be able to, one, inform people about what they were actually exposed to, and two, take the appropriate action if it was a misuse.

Mr. LYONS. Mr. Chairman, if I could, just to amplify on Dr. Goldman's comments. First of all, we concur in the concern of having a total picture of what pesticide use rates and application rates are. Certainly, that includes what occurs in urban and suburban areas.

Something we did discuss, something very difficult to get a handle on, and EPA has done some work to try and get an assessment of actual use, one of the reasons for expanding the recordkeeping requirements with regard to agriculture is so we can finally begin developing actual use data for the purposes of setting tolerances and moving toward a more scientifically sound basis for setting those tolerances.

Lacking that information of course in the past we have been used to making assumptions about maximum-use rates, and we are operating under the assumption that in fact use rates aren't nearly as high as might be provided for in the label and that is a false assumption. Having actual data would provide us a mechanism then to plug real-use data into the tolerance-setting process, and we think that would in the long run be beneficial from the standpoint of agricultural production.

Mr. STENHOLM. Mr. Smith.

Mr. SMITH of Oregon. Thank you, Mr. Chairman.

I want to, first of all, compliment you on what I think is a realistic analysis of these bills, especially with your statement that we should move this in a package and not separate it between committees of authorization. I think it is most important that we do that, and I thank you for that, what I consider to be sound judgment.

Mr. Lyons, how much input did Agriculture or your office have in preparing this bill?

Mr. LYONS. I can assure you, Mr. Smith, this has been full contact policymaking. We have been in there scrapping, as well as FDA, EPA, every step of the way. In fact, I would tell you that one of the reasons for the delay is we debated at length a number of the provisions that were finally incorporated in the administration's bill.

Mr. SMITH of Oregon. Evidently you lost a lot. That is a comment, you don't have to answer that.

Sorry, Jim.

Mr. LYONS. Jim Aidala, said I won too much.

Mr. SMITH of Oregon. Mr. Lyons, what is the intent of the citizen suit provisions?

Mr. LYONS. Well, let me first of all clarify, the citizen suit provisions would not apply to agricultural producers. That was something that we were insistent upon as a USDA position.

I think there was general agreement that producers have enough to worry about these days. They certainly don't need to worry about citizen suits and questions about their compliance with the law.

The citizen suit provisions were recommended as an additional enforcement mechanism, simply stated, and as a way to ensure compliance with FIFRA and FFDCA provisions.

Mr. SMITH of Oregon. In that respect—and I appreciate that straightforward answer, because I think that is exactly what this is about, it is about an enforcement procedure. EPA has testified in earlier hearings that they are understaffed, that they don't have an enforcement program that they can utilize properly.

So here we have a situation in which we are trying to pass Federal legislation and we are saying at the same time we can't staff the enforcement side of EPA, so we got to have citizen suits which will invite lawsuits all over the country which, in many cases, the Federal Government will have to defend at great cost. And we are substituting enforcement of EPA policies by shifting the burden, an unfunded mandate, to citizens who have to hire attorneys to enforce the very EPA laws that we are passing in this legislation.

Is that a fair analysis, Dr. Goldman?

Dr. GOLDMAN. Well, it actually doesn't work that way. The citizen would not be required to get involved if they didn't want to. But the citizen would be allowed if they wanted to, to shoulder part of the burden of governmental enforcement. There is no doubt of that.

We believe at the EPA that citizen suits provisions are successful ways under other environmental laws of augmenting both Federal and State enforcement actions. They don't bring new causes of action under FIFRA. They are only used in cases where the Government would have to take an action in the first place. That is, if the Government is failing to take an action that is mandatory.

Under our provision, the citizen would first have to give 60 days' notice both to the alleged violator and to the Government, and if the Government were to take action or if it were found to be groundless, there wouldn't be a suit. The suit would be filed in a Federal District Court and it would be up to the court to decide if the citizen actually had any standing to file the suit. And if there were frivolous or groundless suits, they would be subject to the sanctions of the court.

So we see this as a way of actually extending our enforcement efforts and not creating new unfunded mandates at all.

Mr. SMITH of Oregon I appreciate that opinion. I must tell you I have a separate opinion of what will occur with the citizen suits. And that brings up the question of deadline suits, and this whole issue of sunset.

Here again we are trying to move past what may be EPA's hesitancy or delay by sunseting these provisions.

You mentioned in your testimony in 15 years, and I understand that there is a small extension available. But the registration just disappears, and therefore if EPA doesn't act, then the penalty is on the person who applies for registration or whatever. Therefore, we are punishing people in the private sector for the delay of EPA. Why should we do that?

Dr. GOLDMAN. There are actually two separate provisions. One is the sunset provision that has to do with registrations being renewed every 15 years. This is not a drop dead provision. This is simply a provision to, on some kind of an orderly cycle, keep the registrations up to date so that we won't be in the position ever again that we were in 1988, which was kind of the equivalent of everybody in New York City decides to get a driver's license on the same day.

The other issue is the issue of tolerances, and our transition from the tolerance setting process that we have today to the health-based standard that we are proposing. And in that case, what we have done is we have set the agency on a set of deadlines to accomplish that, but we have also given the registrants and others the ability to intervene if for some reason we are having a delay in accomplishing that. And there are no tolerances under that provision that would go away without the agency twice making the finding that those tolerances were not safe.

Mr. SMITH of Oregon. Dr. Goldman, this legislation provides that you may be sued if you don't comply. And this is a drop dead proposal.

Dr. GOLDMAN. We are willing to make a firm commitment to a set of deadlines in this program, and I think it is time for the pesticide program to be willing to do that at the EPA.

We are willing to make firm commitments and to stand by them under the threat of a suit, if we don't make our deadlines. And I think that is only fair.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Thank you, Mr. Chairman.

A great deal of my concern centers around the proposal that would no longer allow the consideration of any benefits after 5 years.

And the problem with this, I think, is fairly obvious; that there will be some public health benefit that is going to be generated by the use of certain materials that might propose some very insignificant risk to the population at large. As an example of this, we had a Deputy Assistant Administrator from EPA who testified on May 5, at this subcommittee, about the use of malathion, for medfly eradication, and he stated directly that the EPA came to the conclusion that the benefits that would be derived from the use of malathion would far exceed the risks.

And now we have EPA, setting aside what was accepted policy as late as a month ago, and stating that we no longer will allow the consideration of benefits. Do you not expect that at times there are going to be situations where benefits are going to outweigh the risks?

Dr. GOLDMAN. We are not setting aside the policy under FIFRA for making risk-benefit determinations for pesticide registrations. And the kind of situation that you are talking about, medfly control in urban areas, would still under our proposal involve risk-benefit considerations.

What we are proposing to do is in the area of food safety move to a benefits-only determination. And I am going to read to you from the National Academy of Sciences report; I think this is important: "To ensure that infants and children are not exposed to

unsafe levels of pesticide residues. The committee recommends that EPA modify its decisionmaking process for setting tolerances so that it is based more on health considerations than on agricultural processes."

They go on to say: "Children should be able to eat a healthful diet containing legal residues without encroaching on safety margins." This goal should be kept clear. And that is exactly what we are aiming for in terms of how we set tolerances.

Mr. DOOLEY. Why do we have to have a provision then that ensures that we will never be able to consider any benefits, even when there could be some potential health benefits?

I mean, it is an arbitrary line that you are drawing in the sand. And furthermore, I point out that the people from the National Academy of Sciences who testified here, could in no way state that our children and infants in this country are at risk from the products that they are consuming.

And they, furthermore, pointed out that under the testing protocols that are currently being utilized by the EPA and by FDA to determine what level of risk a potential pesticide might pose, is lacking in providing us accurate results.

And I would be interested to know how the FDA and EPA in regard to infant exposure and prenatal exposure, how are we going to put in the testing protocols that are going to give us any reasonable certainty of what actual risk is going to be posed?

Dr. GOLDMAN. A couple of things: One, we are willing to discuss with the committee the possibility of crafting an exception that would allow a pesticide to be registered if there really is a trade-off in terms of a health, health trade-off. That is, if there is a public health benefit to the presence of the pesticide on the food, we are more than willing to discuss an exemption there.

Second, you are right, there were a lot of recommendations from the National Academy of Sciences report, only some of which we are addressing legislatively. The testing issues that you mentioned in terms of improving our ability to detect the health risks that children especially are susceptible to, we are pursuing very aggressively with the FDA, with others in Health and Human Services, and we have already issued some new guidelines for both neurotoxicity and endocrine toxicity.

We are working on immunological toxicity guidelines and we are working on some of their recommendations having to do with exposures to carcinogens in utero, to see whether or not there is value added in looking at that. And that is one of the things that I think we alluded to in the bill, which is that we really should have those kinds of data.

If we don't have those kinds of data, then we need to take other measures to ensure that children are protected.

Mr. DOOLEY. What is the criteria you are going to use to define a safer pesticide or a less risk pesticide?

Dr. GOLDMAN. We do have some criteria that we have put forward already administratively in terms of our registration program, because we are already giving the safer products higher priority. But what we are looking at there is safer from the standpoint of food residues, worker exposures, environmental exposures, degradation of groundwater, a number of issues that we are looking

at in terms of the arguments that are brought forward by the registrants that their product is indeed safer.

And we are actually finding that even with just an administrative action saying that we will give those pesticides higher priority, that already is providing an incentive to the registrants to bring things forward more rapidly.

Mr. STENHOLM. Mr. Lyons, I understand you have another commitment, so whatever time you need to leave, feel free to get up and leave.

Mr. Elworth will stay to answer any questions for the Administrator.

Mr. LYONS. Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman.

I am interested in following up the line of questioning, started by Mr. Smith.

Back in 1988, we approved reregistration. How are we doing in getting reregistration completed?

At this point, give me a year in which you think we will complete reregistration.

Dr. GOLDMAN. I will tell you how we have done, we completed the first three phases of reregistration on time. And what that had to do with is issuing some 440 comprehensive data call-in notices, and then in response to those data call-ins, receiving 19,000 studies in support of reregistration.

Of these, we reviewed more than 11,000; and for list A, the food-use chemicals, we have reviewed 6,500 of 8,800 studies.

Mr. GUNDERSON. OK.

When do you think we are going to be done?

Dr. GOLDMAN. Can we put the table back up that shows—

Mr. GUNDERSON. I have only 5 minutes.

Dr. GOLDMAN. I understand.

As we are currently scheduled at our current level of funding, we will be done in the year 2004.

Mr. GUNDERSON. 2004?

Dr. GOLDMAN. 2004. These are with so-called reregistration eligibility documents. Some of the product reregistrations will lag behind. If you understand the process, first we do the active ingredients with the so-called "REDS." Then we follow behind with reregistering products.

Mr. GUNDERSON. In 1988 when we passed reregistration, when was our goal for completing the process?

Dr. GOLDMAN. The goal there is on the map, it is fiscal year 1998.

Mr. GUNDERSON. 1998? So 6 years late on this process?

Dr. GOLDMAN. Six years delayed. If we are successful in achieving additional fees, we will be 3 years behind schedule.

Mr. GUNDERSON. You are asking for more fees for reregistration?

Dr. GOLDMAN. That is correct.

Mr. GUNDERSON. How much are you asking for that?

Dr. GOLDMAN. Basically, we believe that we are some \$20 million short.

Mr. GUNDERSON. Annually or totally?

Dr. GOLDMAN. Totally.

Mr. GUNDERSON. Totally. And how much are you asking for the registration sunset provision in your legislation?

Dr. GOLDMAN. It is about the same level of effort as we currently carry out. We are proposing that most of those other activities be carried out within our existing resources.

Mr. GUNDERSON. So you believe that once you have done the re-registration process, that you can do all the registration within the 15-year sunset cycle at no additional cost?

Dr. GOLDMAN. We believe that we can do that activity. Wait a second.

Mr. GUNDERSON. Doesn't your bill have a fee?

Dr. GOLDMAN. What we are basically talking about is that the base budget that we have now, including our current reregistration program, is what would be required to sustain the efforts over the long term, including being able to every 15 years renew registrations.

Mr. GUNDERSON. How much additional revenue through fees are you anticipating in your proposal to fund this process?

Dr. GOLDMAN. Basically, we are talking about \$15 to \$20 million per year for the sunset provision, and about \$14 million per year that we are now spending on reregistration.

Mr. GUNDERSON. So we have a—

Dr. GOLDMAN. And those are separate amounts.

Mr. GUNDERSON. \$14 million per year now is being—

Dr. GOLDMAN. For reregistration activities.

Mr. GUNDERSON. So you anticipate that we will more than double that to \$34 million a year, based on your present projections of the cost annually?

Dr. GOLDMAN. In the interim, what we would be doing is tolerance reviews, because the reregistrations under the sunset provision wouldn't kick in right away.

Mr. GUNDERSON. Have you got a fee for that, too?

Dr. GOLDMAN. And that is factored into what we are asking for in the fees.

Mr. GUNDERSON. That is part of the \$20 million in additional money?

Dr. GOLDMAN. That is probably a little bit above and beyond the \$20 million in additional money. The \$20 million we are talking about is to move the graph that you saw there where we complete the process in 2004 to 2010. And that is simply the shortfall in our current program under FIFRA 1988.

Mr. GUNDERSON. So that is a one time fee to do that? Then you are saying that—

Dr. GOLDMAN. That is a one time.

Mr. GUNDERSON. In the sunset provision you need \$20 million annually, now you are saying for the tolerance review you need x amount in addition to that. All I am trying to do is get at truth in budgeting. If this is your goal, let's understand what we are going to ask for in terms of annual fees to achieve this.

Dr. GOLDMAN. I am going to turn this over to Jim Aidala.

Mr. AIDALA. There is basically three different things. First of all, we need to complete reregistration. Because technically right now under the law, our ability to impose reregistration fees expires in

1998 when the deadline was set, as you mentioned. There is a shortfall.

Roughly speaking, we would expect to pay for reregistration by just continuing on that kind of base level fees that are currently being imposed on the community for reregistration, \$14 million a year as set in the act.

Mr. GUNDERSON. You can complete this by 1998 with \$14 million or no?

Mr. AIDALA. No, obviously not. That is the difference in the two charts, that we have the shortfall made up——

Mr. GUNDERSON. The yellow light is on; we have to go fast.

You have \$20 million in new dollars for that.

Mr. AIDALA. After reregistration is completed, what will sunset cost? Sunset is in a sense the same as reregistration was. We envision that for sunsetting, there would be approximately \$15 to \$20 million a year, and the reason that number is higher is because this \$14 million number was set in 1988.

Inflation does happen, and so that is why that number is a bit of a range. So basically, the fees imposed for reregistration expire when reregistration is completed, the sunset comes up and it is roughly the same number.

Mr. GUNDERSON. \$20 million for tolerance review?

Mr. AIDALA. And for tolerance review, that will be something that will have to be completed within 7 years after enacted, according to these provisions. That will be an additional cost. That has not been costed out. That could be an additional cost above the sort of—again in the \$15 to \$20 million range. Obviously, as we continue that exercise, we can provide that information for you.

Mr. GUNDERSON. If you want us to authorize the fees, we have to know what we are talking about. So you will get back to us on that.

[The information follows:]

**THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S RESPONSES FOR
INFORMATION REQUESTS FOR THE JUNE 15 HEARING RECORD TRANSCRIPT**

The Administration's fee proposals provide (1) adequate funding to accelerate the current FIFRA '88 reregistration program, and (2) fees to operate new authorities, as described below.

1. FEES TO MEET CURRENT REREGISTRATION PROGRAM NEEDS

\$48 million is needed in order to complete reregistration decisions three years earlier than EPA predicted under the current budget (2001 instead of 2004), review submitted studies more quickly to identify risks sooner, and help avoid the need to terminate on-board staff needed for reregistration.

- o \$20 million would cover the shortfall from FY 1995 through FY 1997 through a combination of supplemental active ingredient fees and product reregistration fees, as outlined in the pending legislative proposal.
- o In addition, \$28 million is needed for FY 1998 and 1999 through continuation of product registration maintenance fees for two more years.

2. FEES FOR NEW AUTHORITIES

The proposed legislation also provides for new fees to help operate new programs in the areas of: (1) registration renewal/sunset; (2) new tolerance requirements; and (3) pesticide export. In addition, a small fee is proposed to offset operation of the repository for reference standard for pesticides. Estimated incremental costs for the major program areas are shown in the following table. These figures have not been subject to wide review and are subject to change, but give a general idea of the order of magnitude of expected costs of proposed program changes.

INCREMENTAL COST PROJECTIONS*
(Dollars in Millions)

	<u>Annual Avg. for 1995-1999</u>	<u>Average Future Year</u>
Registration Renewal/Sunset	2.0	17.8
New Tolerance Requirements	12.6	6.1
	-----	-----
TOTAL	14.6	23.9

* Preliminary estimates of incremental costs.

Costs are shown in constant 1994 dollars, without accounting for future inflation, and assume continuation of current levels of appropriated funds for FIFRA '88 reregistration. The Administration's proposed legislation does not specify particular fee structures or amounts for these activities. A number of options are possible, and we intend to work with Congress to develop equitable funding mechanisms and fee structures. Beginning in 2000, for example, some or all of the total program costs could be met through continuation of product maintenance fees and/or active ingredient fees at the time of sunset/registration renewal reviews. In addition, the Administration's proposals would authorize the Administrator to cover the cost of some of the export-related activities through fees imposed on the registrants. The range of covered activities has not been determined and costs for export-related activities are not included in the table.

We look forward to working with the Congress to develop these new programs and to meet the resource needs associated with their implementation.

Dr. GOLDMAN. Well, we actually would like to work with the committee on that issue, because we understand that over time the issue of fees has been a very important issue for you.

Mr. GUNDERSON. That is a guarantee.

I am out of time, so I will have to ask my other questions later. Thanks.

Mr. STENHOLM. I recognize Mr. Smith for a statement.

Mr. SMITH of Oregon. Mr. Chairman, I just want to take just a second to correct the record here, before this hearing goes any further.

Dr. Goldman read from the NAS study, "Diets in Infants and Children." She read to you a portion of a paragraph which did not include the total essence of the statement she read to you: "To ensure that infants and children are not exposed to unsafe levels of pesticide residues, the committee recommends that the EPA modify its decisionmaking process for setting tolerances so that it is based more on health considerations than on agricultural practices." That is what she read to you.

She didn't read to you the next sentence. The next sentence says: "These changes should incorporate the use of improved estimates of exposure and more relevant toxicology, along with continued consideration of the requirements of agricultural production." That is the full statement.

I would like that read in the record.

Dr. GOLDMAN. We agree with that, and, in fact, the next sentence then goes on to say: "As a result, human health considerations would be more fully reflected in tolerance levels."

The only reason for abridging the paragraph was to save time for the committee. We fully agree with that.

Mr. SMITH of Oregon. Thank you.

Mr. STENHOLM. Let the record show there is full agreement on the paragraph in question, and those immediately preceding and those following.

Mr. Inslee.

Mr. INSLEE. Thank you, Mr. Chairman.

Dr. Goldman, I want to take this opportunity to thank you and the whole agency for your efforts to secure an approval dividend for the wheat farmers, the folks particularly in the State of Washington.

As you may know, this is an issue of a great deal of attention both myself, and my neighbor to the east, Speaker Tom Foley, and the Speaker has asked me to specifically thank you and express our mutual concern and hope you can move the dividend as soon as possible. This is critically important because, obviously, this has real life consequences for folks in central Washington.

So again, I want to thank you and encourage you to continue moving the dividend registration with urgent speed.

Dr. GOLDMAN. Great. We do expect to have that decision made by the end of August, and it is moving at great speed, actually.

Mr. INSLEE. Thank you.

A question: Do you have any idea what percentage of total food products purchased by American consumers is organic or at least they perceive them to be, "organic"—having no pesticide?

Does anyone on the panel have any idea about that?

Dr. GOLDMAN. I believe it is quite a small fraction of the food supply. I can't give you the number, but we could probably try to get it. It might be difficult to determine.

[The information follows:]

The U.S. Department of Agriculture (USDA) Agricultural Marketing Service estimates that approximately 1% of the nation's food supply is "organically" grown, accounting for sales of approximately \$1.5 billion.

One major difficulty in arriving at such an estimate is the lack of a uniform, consistent definition of the term "organic." The National Organic Standards Board, established under the 1990 Farm Bill to set the national standards for organic produce production, is working to develop a national definition and to establish national standards for organic certification. These standards will be implemented by the USDA. In developing the definition and standards, USDA is working to compile a list of "organic pesticides" that are effective in controlling unwanted pests but benign to humans, wildlife, and the environment.

Mr. INSLEE. I assume it is quite a small fraction. And the reason I ask that is that it being a small fraction, I have heard several comments about Americans' distrust of the system and distrust of the food chain and fear of the food chain. And yet, at least from my observations, those who have opted out of the food chain process that we have for the most efficient production of food in this country, is very low, which would indicate to me that Americans really do have a pretty high confidence level in their foodstuffs.

And I would just like your comment in that regard. Why do you believe there is this great distrust, other than outside of the CBS studios of American food products, and yet 90-some percent of people buy the food when they have some other alternative? Why is that?

Mr. TAYLOR. I will try an answer to that.

I think you are right, there is perhaps a little bit of a duality in the public mind on the issue of confidence in the food supply. Because people do go to the grocery store every day, they buy food and they consume it, and on most days, most people don't think about the issue of food safety. And that is an indication of some basic level of confidence.

I think the issue arises, and the way we have seen it arise publicly with such devastating consequences has been, when problems arise, when—whether it is an investigating reporter or when an individual consumer is able to point to a situation in which a problem exists that the system is not adequately dealing with.

My personal opinion is that the Alar situation was not about the hazards of that chemical so much as it was about the system apparently being unable to answer the question for people.

There was a question about carcinogenicity. The system, for a set of reasons that I think have to do in part with the nature of the law, was unable to respond to the question. And that is why people panicked, because there wasn't an answer.

I think you can look at any number of other instances in which outbreaks of food-borne illness have caused great public concern. It is not a day-to-day concern. People would rather not think about food safety.

But when a problem exists and it is apparent that it was a preventable problem or a problem that needed an answer and that answer is not available, I think people do react and I think that does undermine confidence.

Mr. INSLEE. Well, would you agree with me that perhaps one of the reasons is all of us, being humans, as policymakers, at times tend to watch the TV screen instead of looking to what our constituents do in their lives in the grocery store, which is to buy foodstuffs produced under this system?

And my concern, frankly, is that some of our policy is driven more by that television screen than what Americans think. And I just—I mean is that a—is that a rational concern for us on making policy?

Mr. TAYLOR. We don't want to be driven by the television screen. I think we want to be driven by whether we have a good answer to the question, are we doing what the science tells us and what our available technology tells us it is reasonable, feasible to have done, to prevent food safety problems? And there are areas in

which the system needs to be improved so that we can answer that question satisfactorily.

It is not to deal with a food safety crisis. It shouldn't be in response to sensational reporting, but have we got a good answer to that question, are we doing everything that it is reasonable and feasible to do with the tools available to prevent problems?

Mr. INSLEE. Let me ask if I can, as far as the risk-benefit issue that we have talked about. I have a concern that in the administration's proposal that the agency will not be able to really judge risk. And let me tell you what I mean by that.

Let's assume that there are two risks associated with foods. One risk is a potential carcinogen, let's just say a potential carcinogen at the moment, but let's say another risk is if that potential carcinogen is not used, there will be a risk of calcium deficiency, let's say, from a failure to eat green vegetables in the American public, particularly in youth.

Under the administration's proposal, as I understand it, the agency would be prohibited from considering the risk of calcium deficiency to young people, and because they would be mandated to look at only the other risk associated potentially with pesticides. Now, I have three children and I would prefer the agency to be able to judge both risks and make a judgment decision based on which is the best way to approach those two risks.

And I think that once we talk about benefits and risk, we are really talking about judging two different risks. I think there is a major problem with the administration's bill in that regard.

I would like your comment.

Dr. GOLDMAN. Well, that is the very reason why we have given the 10-year time period and the ability to give temporary tolerances if indeed there are transitional problems with moving from the system we have today to a health-based system for setting tolerances. Now, in our heart of hearts, we actually don't believe this is going to happen, because we have never seen a situation where a change in pesticide usage has had that kind of a profound effect.

But we also felt the need to have a safety net and to build into the process some way to handle the situation if, shall heaven forbid, we end up with having that kind of a disruption in the food supply. Now, obviously if we were to find that if push comes to shove and there are no alternatives, which again we seriously doubt because there are many alternatives for controlling most of the pesticides in this country, we might well need to come back to Congress and talk to you about it. But at this point in time, we think we have allowed the time and we have a safety net built in to ensure that that kind of thing would never happen under our proposal.

Mr. INSLEE. Thank you.

Mr. STENHOLM. Mr. Ewing.

Mr. EWING. Thank you, Mr. Chairman.

I practiced law in a rural community for 25 years, so I have a little feel for lawsuits. I am concerned about the citizen suits provision and what safeguards you have against nuisance suits.

You mentioned a few things, but I really am not sure that there is anything built into your proposal that would prevent them. Would you address that again, Dr. Goldman?

Dr. GOLDMAN. Yes. I mean, basically there are a couple of issues here: One is that the citizen suit is only for an action that is mandatory for the Government to do in the first place.

This does not create some new action that the Government could take action over or that citizens can take action over.

Second, is that there is the requirement for the 60 days' notice, and if the State or Federal Government responds to the notice and clears up the issue, say, the person who wanted to file the suit just has a misunderstanding about what happened, the problem could be cleared up within that 60-day period.

And then third, the court, the Federal District Court, has to be willing to hear the suit. And if it is totally frivolous—

Mr. EWING. Pardon me for interrupting, but I don't have a lot of time. That is true, but there are so many things that the Federal Government mandates that aren't being enforced, and you are saying in this situation, though, it opens that all up, anything that might be mandated, for them to bring a suit.

Now, the 60-days' notice is nothing when dealing with the Federal bureaucracy. Go to central Illinois, send the notice to Washington, you won't get it cataloged in 60 days, let alone an answer.

Dr. GOLDMAN. Actually, the primary enforcement arm for the EPA, for FIFRA, is the States, and primarily the State departments of agriculture, who do have a presence in all of the communities in the country.

Mr. EWING. Let me just say, I think that is very dangerous ground you are treading on.

My second question deals with the recordkeeping on nonrestricted-use pesticides. You are expecting that to be done by each producer?

Dr. GOLDMAN. Basically, the recordkeeping would be required for agricultural producers and also for commercial applicators.

Mr. EWING. Is there any cost-benefit ratio for the cost of doing that, the costs that you would have, in enforcing it, and keeping records on it, as to the benefit that you would get from it? Now, we are talking about nonrestricted use.

Dr. GOLDMAN. Basically, the records would be, it is very useful to the agency in not only understanding more clearly exactly how pesticides are used, as Mr. Lyons explained, which is useful in a number of ways, but also if we ever do take an action—

Mr. EWING. But is there any cost-benefit ratio for that cost to the producer?

Dr. GOLDMAN. In terms of the producers, it is our belief that agricultural producers already keep records of their pesticide use for a number of reasons, not the least of which is a good business practice.

Mr. EWING. I am sure they do keep financial records on it, but not necessarily where it is sprayed, where it is used, in which fields, particularly nonrestricted use.

Did you ever think that you might gain that information by getting it from the supplier of those chemicals to the producers and not every individual producer?

Dr. GOLDMAN. Well, in the experience in States where they have put in place recordkeeping provisions, what they have found is that it does make sense for the commercial applicators and for the pro-

ducers to keep records. Where we do have recordkeeping provisions already in States, are in California, Texas, and Kansas, and we do not hear reports from our State regulator partners that this creates a problem.

In fact, the reports that we hear from our partners in those States is that there are considerable advantages in a number of ways for having those, including just having a better understanding of what kind of pesticides are used.

Mr. EWING. I have a concern generally that we are setting rules and regulations that will cause the disappearance of a number of the weapons in the farmer's arsenal, even those that aren't considered restricted use, and that the policy of a number of administrations to encourage cheap food, reasonable food, in this country, will be damaged by that.

Now, there is a cost-benefit ratio there for all of this and my question would be, because we all represent not only people who eat food but the producers who create it, is there anybody on your staff who has any hands-on experience with real agricultural production that is making these rules?

Dr. GOLDMAN. There absolutely is. And the other thing I think you should look at carefully, because I think that this gets right to the heart of the issue that you are concerned about, is the provisions that we have crafted to encourage minor-use pesticides, new safer pesticides, to speed the registration programs. Because although there have been policies by former administrations to increase food production, there have also been policies that have wound up actually hurting the farmers by reducing the supply of available pesticides. We are trying to rectify that with our FIFRA proposals.

Mr. EWING. I would like to have you provide for the record substantiating evidence or documentation about who is working on this and what their hands-on experience was, so that all of us can see that.

Dr. GOLDMAN. Certainly.

[The information follows:]

EPA PESTICIDE PROGRAM STAFF WITH AGRICULTURAL EXPERIENCE

Many of EPA's Office of Pesticide Programs (OPP) staff have had "hands-on" experience with agricultural production. Their knowledge of production agriculture is invaluable in considering the needs of agriculture in EPA's regulatory decisions. In addition, EPA staff routinely meet with and make presentations to agricultural grower groups, both to provide information on EPA's pesticide program and to hear growers' concerns. We also have a very close working relationship with the U.S. Department of Agriculture, in developing legislative/regulatory initiatives and considering the impacts of decisions on agriculture. Public comment is routinely invited on EPA regulatory decisions, and this also provides an avenue for input from the agricultural sector.

A quick, incomplete survey of OPP's approximately 760 staff identified 76 staff with previous or current experience in agricultural production. Fifty-seven (57) staff reported experience operating a farm either as an adult (35), or through growing up on a farm (22). Of the 76 staff who responded to the survey, 30 reported receiving advanced education in an agricultural field. Thirty-seven (37) have worked in industry and/or the public sector in agricultural research or extension.

A few representative staff experiences are described below.

Phil Hutton is a product manager with OPP's Registration Division (RD), and has a degree in entomology. He has twenty-eight years of experience in farming, and still lives on the same farm, raising horses, cattle, oats, hay, and sweet corn.

Neil Anderson is an agronomist with the OPP's Biological and Economic Analysis Division (BEAD). He grew up on family farm in New York, raising beef cattle, corn, alfalfa and grass hay, and oats. He went on to obtain a degree in agronomy, then worked for three years as a research technician testing experimental insecticides, herbicides, and fungicides for Ciba-Geigy, and two years with the University of Maryland in research and extension, before coming to EPA.

Pat Cimino is with OPP/RD in the plant pathologist/entomologist series. She worked for five years with Union Carbide and Rhone Poulenc in marketing and product development for agricultural pesticides, working directly with growers to determine how to use products effectively and safely. She had responsibilities for an extensive product line and worked in many commodity markets. She had previously spent five years with the University of Maryland in vegetable research, including serving on the university's vegetable crop improvement research board with local farmers.

Philip Poli is with OPP's Special Review and Reregistration Division (SRRD), working on special reviews. He has a degree in animal science husbandry, has raised cattle and hogs, and was employed as a USDA Federal Meat Grader.

Eugene Wilson is with OPP/RD, and has degrees in agricultural sciences, mycology and plant pathology. He presently owns and operates a 90-acre farm in West Virginia, producing forest products and hay. In his youth, he helped operate a livestock farm, including beef cattle, dairy cattle, swine, horses and poultry. He has also worked in pesticide research with Shell Oil Company.

James Breithaupt, an agronomist/scientific reviewer in OPP's Environmental Fate and Effects Division (EFED), grew up on a farm in Louisiana, where he helped raise soybeans, cotton, and grain sorghum for twelve years. He has applied pesticides, conducted research on sugarcane fertility, and worked for a crop consultant.

Mark Dow, a supervisory biologist with OPP's Health Effects Division (HED), worked for about ten years in beef cattle production with his father-in-law. He has an entomology/parasitology degree, and has done research on control of external parasites of poultry, horses, and beef cattle.

Alan Goozner, a statistician with OPP/BEAD, has growing experience with vegetables and fruit, selling retail at roadside. He also worked on chicken farms vaccinating pullets, and as an egg candler. He was a member of a 4-H club in New Jersey.

Paul Schroeder in OPP/RD was born on a combination dairy and poultry farm in New Jersey. He attended Rutgers University and has a degree in entomology. He has worked with the Land Grant system and industry in research and extension, including managing a 120-acre research farm.

Ron Kendall in OPP/SRRD worked on all aspects of a 20,000 bird poultry operation in Massachusetts for more than eight years and spent two years in Haiti as an agricultural extension agent.

Mr. EWING. Thank you.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. Thank you very much, Mr. Chairman.

I appreciate this hearing. I have a lot more questions in regard to the proposed legislation than I have time for, but I have one.

In the bill, you address what has been known around here as the "circle of poison." And I have a little question I would like to ask Mr. Elworth or anybody else that wants to answer it.

The way I read your proposal, if a firm here in the United States prepares a chemical for export to a country such as Japan or any other country which approves pesticide use, whether it is European or any other, and it is to use solely on their crops, not for export to anyplace, it can't be approved under your bill.

Mr. ELWORTH. No, that can be approved if there is an export tolerance—an import tolerance to bring——

Mr. VOLKMER. Never went for anything here, it is not going to be used in the United States.

Dr. GOLDMAN. It can be approved if it has a registration in three other countries.

Mr. VOLKMER. Three, three, it is only going to be used in one.

Now, where are you going to get the second and the third? What is the purpose?

Dr. GOLDMAN. If the pesticide has only been approved in one other country, we would be concerned about whether or not that registration meets the standards that we would want the pesticide to meet. We are willing to have discussions with this subcommittee about whether there are alternative ways to craft this, but we feel that we must be very firm about making sure that even if a pesticide has never been registered in the United States, that it meets the kind of standards that we would expect for the standards for a pesticide that would be used in our own country.

Mr. VOLKMER. Well, let me ask you this then. How many chemical companies do you know of that only operate here in the United States, major ones?

Dr. GOLDMAN. How many what?

Mr. VOLKMER. That only have plants here in the United States?

Dr. GOLDMAN. Pesticides generally have world markets.

Mr. VOLKMER. The plants, I ask about the plants.

Dr. GOLDMAN. How many plants? I have to get back to you with that answer. I don't know how many plants in the United States.

Mr. VOLKMER. Doctor, you are missing the whole point. Ciba-Gelsy, Inc. doesn't just have plants in the United States. They have plants in the whole world. Other manufacturing companies have them all over the world.

Now, what you are telling those companies is that they can't manufacture it here in the United States, but they can go ahead and manufacture it in Belgium or South America or anyplace else and sell it to that same country, is what you are doing.

Dr. GOLDMAN. No, that is not what we are telling them.

Mr. VOLKMER. You are losing jobs here in the United States, is what you are doing.

Dr. GOLDMAN. That is not true.

Mr. VOLKMER. It is true.

Dr. GOLDMAN. Absolutely not. We feel very firmly that the U.S. pesticide industry makes the widest and broadest array of products of any industry in the world. And if we have a pesticide that isn't fit for use in this country, there is no reason that we need to export that pesticide in lieu of all of the other available products that we manufacture in this country.

Mr. VOLKMER. I am not saying not for FIFRA use in this country, but designed for use on a crop in another country, and don't ask me how I know about it, because I know of a product made in my hometown right now by a chemical company that is only being used in one country. And it is Japan, and it is on rice.

And what you are proposing here is to shut down that operation and put those people in my hometown out of work. And what it means is American Synametic can go someplace else and have it manufactured in offshore plants and those people will get the work and the stuff is still going to go to Japan.

Dr. GOLDMAN. What I am trying to say, though, is what we are trying to uphold here is a certain standard. We are not trying to be rigid about how we get to that standard and we are willing to work with the subcommittee if you have alternative suggestions for how to get there. But we do want to be very firm about having a strong standard.

Mr. VOLKMER. I don't mind saying that if a chemical, a pesticide or anything else, has been canceled here in the United States, cannot be used here in the United States, and it cannot go overseas, fine. But what you are saying, you are going further than that.

You are even saying that we can't develop for other countries' uses here in the United States, which this product was done. And we cannot develop it because unless it has gone to three countries and been approved in three countries, you can't sell it overseas. That is just what your bill says.

Dr. GOLDMAN. What we are trying to get away from is not a case that you are bringing up where the pesticide was tailor-made for just one country. But a case where the pesticide wasn't brought to us for registration because the company knew it would not meet our standards. And that has happened in many cases. It is an unfortunate reality.

And so we are not trying to write our provision to deal with the situation that you raise as a theoretical situation. We are trying to make sure that—

Mr. VOLKMER. It is not theoretical, it is an actual.

Dr. GOLDMAN. But you understand the difference, we just want to make sure that we are not in a situation where we are exporting things—people wouldn't have even brought to us for a registration because they know they won't meet our standards.

Mr. VOLKMER. All right.

The next question I have is—I have two more, but I think this is a little more important. Do you not address in this bill any problems with importation? And what I am concerned about is today we have, and I agree with it, a push for our children to use more fruits and vegetables in the school lunch program.

Much of that fruit, especially, will be coming from countries that do not register, that can use any kind of chemical they want. And if you are really concerned about children eating grapes from Chile

and other places, then I think we should impose the same thing on them. If they don't register their chemicals, like we require chemicals to be registered, they can't send their fruit in here.

What about that?

Mr. TAYLOR. The standard embodied in our bill, just as in current legislation, is that in order for a pesticide residue to be lawfully introduced into this country on, say, a fresh fruit or vegetable, it must comply with U.S. law. There must be a tolerance that makes that residue lawful.

The problem we have, and the bill addresses this, is that there are and they have been documented, there is room for improvement in our import monitoring and enforcement program.

Mr. VOLKMER. That is correct.

Mr. TAYLOR. The authorities that our bill would provide FDA regarding embargo of products, civil penalties and recall of product, would give us tools to deal with the situation in which imported product comes in. And this happens on an all too frequent basis, where product is held for examination, we test the product, but before we complete the testing, the product is released into distribution. And we do not have tools adequate to deal with those situations.

The embargo, recall and civil penalty authorities that we are seeking would give us some very effective tools to prevent the problem you are concerned about.

Mr. VOLKMER. Are you asking for additional funds?

Mr. TAYLOR. We are not asking in this legislation for additional funds. We spend a very substantial portion of our entire food surveillance activity on imports. Half of the sampling we do of the food supply is on imports.

So we feel that given our overall resource situation, we are applying a significant level of resource to it. We need more effective enforcement tools to make good on that.

Mr. VOLKMER. Well, how are you going to monitor—my time is up, Mr. Chairman. Can I continue this for 2 minutes; 1 minute?

Mr. STENHOLM. We are going to have another round.

Mr. VOLKMER. I will wait.

Mr. STENHOLM. Let's get everybody the first time.

Mr. Allard.

Mr. ALLARD. Dr. Goldman, my office had sent you a letter requesting a justification for the fee increases that you are requesting. You had sent us back sort of a perfunctory response that we were looking into it, you would get some information to us later. Are you getting that information ready so that this committee and other committees can look and see for a justification the fees that you want, you are requesting?

Dr. GOLDMAN. We did get a letter from you asking for a detailed breakdown of how we have spent the reregistration fees. And I did sign off on a detailed response on that to you yesterday, that should be reaching you any moment now.

I was just told it was faxed to you last night. But so you should have a detailed breakdown of how we have spent the reregistration fees to date in your in box.

Mr. ALLARD. Good, I appreciate that.

I have several questions that are on a technical nature as far as the administration's proposal is concerned, as far as FIFRA. And so we will go through as many as we can, then I will be questioning back through the panel. I would like to bring up the others.

I would like to talk a little bit about your pesticide chemical residue provision that you have that is in H.R. 4362, on page 3, line 1 through 7, that requires a tolerance or exemption from a tolerance be granted for all detectable metabolites of the pesticide chemical. Can you answer the question, to date, how many tolerances or exemptions have been granted for pesticide metabolites?

Dr. GOLDMAN. I can't answer you that question. I can get you the information. We certainly do that today.

Today, we look at the metabolites as well as the parent chemical.

Mr. ALLARD. But my understanding is that you don't grant tolerances and the response would be no.

Dr. GOLDMAN. Actually, we do. And we do that in different ways at different times, depending on what the nature is of the analytical technique. But if there is a health concern for a metabolite, then we do make sure that there is not only a tolerance, but also a monitoring procedure so that our friends at FDA can find the metabolite if it is present.

And there are pesticides for which the parent compound has totally disappeared by the time the pesticide is in the marketplace, but it is the metabolite that we are concerned about from a health standpoint.

Mr. ALLARD. Could you provide this committee with those examples of pesticides where you grant—so the way I understand the legislation, is that on all these metabolites, you force the applicant to come in and establish or there will be some establishment of a tolerance on all those metabolites that you can begin to measure. And I see that sort of as a moving target, as our technology changes we are able to break down our chemical equations into better steps.

And how in the world—almost walk back into another situation where we have a Delaney clause, where you have a diminishing value of zero. As we become more expertise and more refined in being able to analyze each step of an equation, we begin to identify these metabolites in more steps in the chemical equation as you go through that.

How are we going to set a limit on the number of metabolites?

Dr. GOLDMAN. I can explain to you how we do that and get you some information.

For the record here, if you will accept it, is a report that I was involved in when I worked at the California State Health Department on a poisoning incident, where hundreds of people were poisoned by Aldicarb sulfoxide in watermelons in California. Aldicarb sulfoxide was a breakdown product of the pesticide that was supplied.

Mr. ALLARD. I understand we can bring up an anecdote, but I am looking at the overall licensing process and approval process.

[The information follows:]

The Administration's legislative proposals will codify in the statute EPA's existing policy and practices in evaluating metabolites for the purpose of establishing and reassessing tolerances. Following is a brief description of the Agency's approach.

It is important to identify all possible metabolites of concern in order to assess dietary risks as part of the tolerance-setting process. This is necessary because in some cases a pesticide may be metabolized into a more toxic form than the parent compound. For this reason, EPA requires plant and, where appropriate, animal metabolism data to support tolerance petitions. Using the results of these studies, EPA determines which metabolites are of concern and therefore need to be considered in assessing the dietary risk posed by residues of the pesticide. The Agency then generally establishes tolerances that cover all of the expected residues, including the parent compound and metabolites, such as tolerances for residues of aldicarb and its sulfoxide and sulfone metabolites. For metabolites that are toxicologically significant and occur at significant levels, a suitable analytical methodology is required.

In some cases, the Agency may establish separate tolerances for metabolites, when this is found to be warranted by EPA scientists. Examples include tolerances established for residues of melamine, a metabolite resulting from application of cyromazine, and separate maximum residue levels for acephate and its cholinesterase-inhibiting metabolite, methamidophos.

In addition, marker compounds may be used in the tolerance expression if the Agency determines, based on data provided, that residue levels of other metabolites of potential risk concern may be determined for use in risk assessment using a ratio of these metabolites to the markers. Careful judgment regarding metabolites to include in the tolerance expression may help improve consistency with international Maximum Residue Limits established by the Codex Alimentarius Commission, and increases monitoring capability in regulatory monitoring programs.

Pesticide Food Poisoning from Contaminated Watermelons in California, 1985

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ABSTRACT. Aldicarb, a carbamate pesticide, is the most potent pesticide in the market and has a LD₅₀ of 1 mg/kg. In the United States it is illegal to use aldicarb on certain crops, e.g., watermelons, because it is incorporated into the flesh of the fruit. Once an accidental or illegal use of such a potent pesticide occurs, there is no easy way for the agricultural or public health system to protect the populace. This paper describes the impact of one such event upon the health of individuals and the institutions of California. On July 4, 1985, California and other western states experienced the largest known outbreak of food-borne pesticide illness ever to occur in North America. This was attributed to watermelons contaminated through the illegal or accidental use of aldicarb by a few farmers in one part of the state. Within California, a total of 1 376 illnesses resulting from consumption of watermelons was reported to the California Department of Health Services (CDHS). Of the 1 376 illnesses, 77% were classified as being probable or possible carbamate illnesses. Many of the case reports involved multiple illnesses associated with the same melon among unrelated individuals. Seventeen individuals required hospitalization. There were 47 reports of illness

involving pregnant women, two of whom reported having subsequent stillbirths. Thirty-five of the remaining pregnant women were followed-up 9 mo after the epidemic; no additional stillbirths were found. To control the epidemic, it was necessary to embargo on July 4 and to destroy all watermelons in the state on July 7 and to effect a field certification program. The epidemic and the costly resultant control measures illustrate the difficulties in assuring the safe use of the most potent pesticide. The use of pesticides is controlled by an elaborate set of crop specific regulations. State and federal regulators use laboratory tests of produce samples to insure that regulations are followed. When inadvertent or illegal applications of pesticide occur in a particular crop, there is no system that guarantees that the public will not be exposed. For most pesticides, the effects may not be dramatic, but when a potent pesticide appears in a widely eaten commodity, the impact on health and the institutions that are designed to protect it can be devastating. This paper describes the course of one such event.

ON JULY 3, 1985, the Oregon Department of Health notified the California Department of Health Services (CDHS) of several cases of possible pesticide illness related to consumption of watermelons that were thought to have been grown in Arizona.^{1,2} At 4:00 A.M. on July 4, a 62-y-old woman on digoxin therapy was treated at a Lake County, California, emergency department for hypotension, severe bradycardia (31 beats per minute [bpm]), atrial fibrillation, diaphoresis, vomiting, diarrhea, lacrimation, salivation, and muscle twitching. She had eaten watermelon about 30 min earlier. Her symptoms resolved following treatment with atropine. Two other family members who had consumed the same watermelon were also ill and had similar though milder symptoms. The treating physician notified the San Francisco Bay Area Regional Poison Control Center, which subsequently notified CDHS.

Later on the morning of July 4, Oregon officials reported to CDHS that aldicarb sulfoxide (ASO), a toxic degradation product of aldicarb, had been detected in several of the melons related to illness episodes in that state and that the origin of the melons was, in fact, from California.^{1,2} Aldicarb, CAS No. 116-06-3, is a cholinesterase-inhibiting carbamate pesticide that is not registered for use on watermelons in the U.S. but commonly used on citrus, cotton, potatoes, peanuts, and soybeans. Within 2 h, calls to 10 California poison control centers, 20 selected emergency departments, and 1 county health department had identified an additional 12 presumed cases of pesticide illness related to consumption of watermelons. This included a group of 4 individuals in Bakersfield who had eaten a striped melon purchased at a roadside stand, a group of 6 individuals who had eaten a striped melon from a Los Angeles-area supermarket warehouse, and 2 individuals in the San Francisco Bay Area who had eaten green melons purchased at different retail stores. These illnesses were investigated by state and local health officials, and arrangements were made for obtaining watermelon samples.

Just prior to noon on July 4, statewide media advisories were issued that warned against eating watermelons, and an embargo was placed on the sale of watermelons throughout California. Usual product recall mechanisms were inoperative because the day was a national holiday. By late afternoon on July

4, case investigations and tracking of sources of melons back through the distribution chains had implicated a single Kern County shipper in several, but not all of the episodes. Subsequently, in the melon from the first known California case, ASO was found at 2.7 parts per million (ppm). The embargo remained in effect for the next 3 d.

On July 7, all watermelons in retail outlets or in the chains of distribution were destroyed because it was impossible to distinguish ASO-contaminated melons from melons free of ASO. A field certification program was implemented on July 10, and the embargo was lifted. Surveillance after that time identified only one further illness episode in California associated with a melon that tested positive for ASO. Product certification was conducted by the California Department of Food and Agriculture (CDFA) and involved testing composite samples of melons from fields for aldicarb and its metabolites. Melons from fields that tested negative were labeled by CDFA to certify that they had been cleared.

Methods

Commencing late on the morning of July 4, the public was advised through the mass media to report any watermelon-associated illness to their local health department. An active surveillance network set up by CDHS on July 5 involved (a) daily calls to California's 10 regional poison control centers and selected emergency departments, (b) daily contact with all local health departments in California, and (c) periodic calls to several western states and the western provinces of Canada. Local health departments were asked to complete and return an illness report form (described below) to CDHS for all cases reported to them. They were also asked to periodically call selected hospital emergency departments within their jurisdiction so as not to miss illnesses severe enough to require emergency treatment or hospitalization.

The CDHS illness report form and a case-definition algorithm were developed based on the expected cholinergic symptoms resulting from ingestion of aldicarb (Table 1). The case definition divided illness reports into three categories: (1) probable, (2) possible, or (3) unlikely, depending on timing of symptom onset, nature and severity of

symptoms, and number of people ill from the same melon.

The CDHS illness report forms were distributed rapidly to local health department officials in an effort to speed collection of uniform case information. The forms included questions about symptoms, time and location of melon purchase, and others who ate the same melon. All reports of illness with date of onset after July 10 were telephoned to CDHS and promptly reviewed by a physician to identify probable poisoning cases from melons bearing certification labels. Additional information was sought from persons who reported illness, if necessary. Samples of melons from probable cases were collected and shipped by local health departments to the nearest participating CDFA or CDHS laboratory for analysis.

Analyses for aldicarb, ASO and aldicarb sulfone (AS) in watermelons were performed by CDFA. In addition, several confirmatory analyses were performed by the U.S. Food and Drug Administration (FDA) regional laboratory in Los Angeles and CDHS's Food and Drug Laboratory. Analyses by CDFA and FDA were performed using liquid chromatography. The minimum detection level was usually 0.2 ppm but ranged between 0.1 and 0.5 ppm ASO. Confirmatory analyses by CDHS were performed using gas chromatography and a method developed by Union Carbide for detecting aldicarb residues in water (method ALDICARB-FPD-WATER(a)).³ The detection level by this method for all aldicarb residues combined was 0.01 ppm.

Selection of melons for testing was completed in two stages. During the first stage, i.e., prior to July 10, attempts were made to confirm the source and extent of the epidemic. The second stage, after July 10, involved sampling melons from fields that had passed the certification program. The theoretical ability of the field certification sampling plan to detect a single, highly contaminated field was quite good, but given the practical limit of detection of ASO, the necessary compositing of samples, and the large number of fields involved, it was still possible that some contaminated melons might have reached retail markets. Therefore, melons associated with "probable" illnesses that occurred after July 10 were assigned top priority for testing.

Active surveillance continued until the end of August 1985. All case reports were reviewed later for completeness, and additional data were sought when needed. Data from individual case reports were then analyzed using the standardized case definition.

In March 1986, an attempt was made to contact by mail and telephone the 47 women who reported being pregnant when they experienced their watermelon-associated illness. Information was obtained on the pregnancy outcome, birthing complications, birth defects, and any other relevant problems. Six of the 47 were lost to follow-up. Of the remaining 41, 2 denied having been pregnant, and 1 refused to participate. The other 38 women

provided information on a standard questionnaire about the outcome of the pregnancy and the baby's health.

Case reports were tabulated in an attempt to identify the geographic source(s) of the epidemic. Illness rates and numbers of illness were mapped by county using SAS/GRAPH, 1980 U.S. Census population denominators, and Tektronix plotter.⁴ In an attempt to pinpoint store chains (and through them, wholesalers and farmers) who might have sold contaminated melons, we compared the frequency with which the various chains were identified by "probable" cases and by "unlikely" cases. Our reasoning was that "unlikely" cases probably approximated a random sample of the population as to their use of the various store chains so that we could analyze the data as one would a case-control study. We calculated odds ratios and 95% confidence limits. This measure of association divides the odds of using a particular store chain by "probable" cases by the odds of using that chain among "unlikely" cases. For rare diseases, it is an estimate of the rate ratio, i.e., the incidence of poisoning in patrons of that chain divided by the incidence in nonpatrons. Distributors that served counties or store chains with high odds ratios would be most suspect as sources for contaminated watermelons.

Because of the difficulty in using the complete case definition given in Table 1, which required asking cases about the occurrence of multiple symptoms in several categories, simpler alternative case definitions were explored using data on symptom rates and onset times.

Results

Active surveillance. Case reports were received for dates as early as June 1, 1985. Table 2 shows the number of case reports received in California for the period of active surveillance (June–August 1985) by case classification. In all, 1 376 case reports were received; 78% were classified as probable or possible pesticide poisoning. The geographic distribution of illnesses was evaluated in an attempt to identify the origin of the contaminated melons, but mapping did not suggest a source or sources. Analysis of stores where melons associated with pre-July 10 illness were purchased showed that there were four major supermarket chains involved. Only one of these had a significantly elevated odds ratio, 1.89 (95% confidence limits 1.00 and 3.56), for "probable" vs. "unlikely" illness reports. However, the watermelon distribution systems were too intermingled to quickly determine the suppliers for this chain.

The majority of incidents (61%) involved one person becoming ill after eating a melon. Twenty-two percent of the reports involved 2-person episodes; 10% were 3-person clusters, and 3% were 4-person clusters. Additional clusters involving 5, 6, 9, and 13 persons becoming ill after eating from the same melon also were reported.

Table 1.—Case Definitions for Watermelon-Associated Illness Outbreak—California, July 1985

Classification of Cholinergic Symptoms	
Group 1: Gastrointestinal Abdominal pain Nausea and/or vomiting Diarrhea	Group 3: Skeletal muscle Muscular weakness Twitching
Group 2: Other peripheral autonomic Blurred vision and/or watery eyes Pinpoint pupils Excess salivation Sweating or clamminess	Group 4: Central nervous system Seizures Disorientation or confusion Excitation
Classification of Illness Reports	
<p>1. Probable case: Melon positive for aldicarb or aldicarb metabolites; onset \leq 2 h after consuming melon; AND ONE OF THE FOLLOWING: Multiple groups of cholinergic symptoms or a single group of symptoms and more than one person ill from the same melon; OR onset between 2 and 12 h after consuming melon, multiple symptom groups, and more than one person ill from the same melon.</p> <p>2. Possible case: Onset less than 2 h after consuming melon, a single group of symptoms, and no other illnesses reported from the melon; OR onset within 2 to 12 h after consuming melon and multiple symptoms or symptoms from only one group</p> <p>3. Unlikely case: Some other cause of illness judged to be more likely; OR any illness with onset of symptoms more than 12 h after eating melon.</p>	

Table 2.—Numbers and Percentages of Watermelon-Associated Illnesses Reported in California, June 1–August 31, 1985, by Onset Date and Case Definition

Case definition	Onset 6/01–7/10		Onset 7/11–8/31		Onset unknown		Total	
Probable	493	(49%)	197	(57%)	2	(8%)	692	(51%)
Possible	269	(27%)	101	(29%)	6	(23%)	376	(27%)
Unlikely	195	(19%)	40	(12%)	0		235	(17%)
Incomplete	48	(5%)	7	(2%)	18	(69%)	73	(5%)
Total	1 005		345		26		1 376	

Note: See Table 1 for case definition.

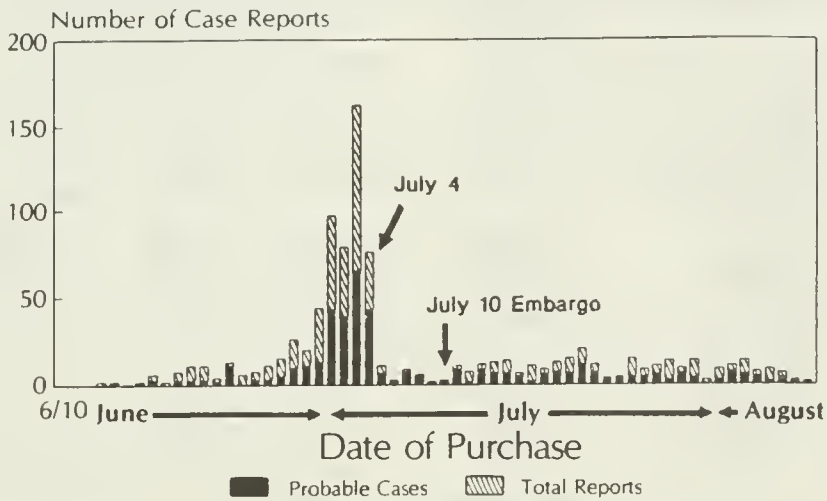
Figure 1 shows the epidemic curve of probable watermelon illness reports within California by date of purchase of melons. The first probable case was reported for a melon purchased June 16; reports rose sharply thereafter. Reports peaked for melons purchased on July 3. There was an abrupt decline in reports for melons purchased after July 4, which coincided with the melon embargo, media advisories, and other measures. Illness onsets for probable cases peaked July 4, and, as with onsets by purchase date, sharply declined after July 4.

Severity of illness. Most people had relatively short-term minor illnesses that resolved quickly; however, some were severely ill. Several reports of cardiac arrhythmias, dehydration, seizures, and other severe illnesses were associated with watermelon consumption before and after July 10 (Table 3). Overall, 17 persons were reported to require hos-

pital admission, 16 of whom were admitted prior to July 10. Of 6 reported deaths, all of which were autopsied, none could be attributed by the coroners to aldicarb/ASO ingestion.

Pregnancy outcomes. Of the 38 women pregnant when they had watermelon-associated illness, 18 were classified as probable cases, 9 as possible, and 10 as unlikely. In one case, the information to classify the illness was inadequate. During the two months immediately after the incident, three pregnancies were investigated. Two near-term pregnancies resulted in stillbirths following acute illnesses associated with watermelon consumption. One pregnant woman had a "probable" illness, and the other had a "possible" illness. Fetal tissues from both stillbirths tested negative for aldicarb and its metabolites (personal communication, Union Carbide Corporation, 1985).

Fig. 1. Watermelon aldicarb illness reports by case definition and melon purchase date California, 1986.



California Department of Health Services

Nine months later an attempt was made to contact the other women who reported being pregnant when they had their watermelon-associated illness. Among the 35 women contacted, 2 neonatal deaths were reported. One was a premature infant born to a mother with "possible" illness, who reported headache and fever 1 wk prior to delivery, raising the possibility that the premature birth and death may have been due to an infection. The second death was due to hypoplastic left heart syndrome; this occurred to a mother with a "probable" illness during the 25th wk of gestation.

Laboratory testing. Of 62 laboratory-tested melons purchased prior to July 10 and associated with illness, 9 (14.5%) were ASO positive. For illnesses associated with melons purchased after July 10, 188 melons were tested, and 1 (0.5%) was ASO positive. In no case was the parent compound aldicarb identified, but some melons contained AS. In addition to the 1 noted aldicarb-positive melon purchased in California after July 10, 2 other aldicarb-positive CDFA-labeled watermelons associated with illness after July 10 were reported in Canada (personal communication, 1985) and Oregon.¹ One of the 3 positive melons found after July 10 could be traced to a particular California field.

Case definition.

The case definition algorithm was compared with symptom reports (Table 4). In general, the 28 with laboratory confirmation of watermelon contamina-

Table 3.—Severe Illness in California Associated With Watermelon Consumption, Summer 1985.

Condition	Number of cases reported	
	Before July 10	July 10 and after
Seizures	3	0
Loss of consciousness	4	1
Cardiac arrhythmia	6	1
Hypotension	4	0
Dehydration	17	2
Anaphylaxis	3	0

Note: Some individuals had more than one of the above symptoms

tion with ASO were more likely to have had symptoms compatible with carbamate poisoning than those for whom melon tests were negative or not performed. Symptoms reported by at least 50% of those who consumed confirmed ASO-contaminated melons included abdominal pain, nausea, vomiting, diarrhea, blurred vision, salivation, sweating, muscle twitching and/or weakness, and disorientation. These symptoms were also found, but with less frequency, among cases classified as probable, possible, and unlikely. Symptom group 1 (gastrointestinal symptoms) showed the smallest differences in reporting between laboratory-confirmed melon

Table 4.—Cases With Various Symptoms, by Case Definition*: California Aldicarb in Watermelon Episode, 1985 †

Symptom	Melon positive‡ for ASO	Illness report classification		
		Probable	Possible	Unlikely
(Total)	28 (100.0)§	689 (100.0)	311 (100.0)	303 (100.0)
Group 1				
Abdominal pain	23 (82.1)	493 (71.6)	212 (68.2)	158 (52.2)
Nausea/vomiting	24 (85.7)	563 (81.7)	250 (80.4)	200 (66.1)
Diarrhea	24 (85.7)	466 (67.6)	179 (57.6)	181 (59.7)
Group 2				
Blurred vision	17 (60.7)	223 (32.4)	31 (10.0)	40 (13.2)
Salivation#	14 (50.0)	128 (18.6)	22 (7.1)	21 (6.9)
Sweating#	20 (71.4)	356 (51.7)	61 (19.6)	59 (19.5)
Group 3				
Muscle//	15 (53.6)	222 (32.2)	41 (13.2)	40 (13.2)
Group 4				
Disorientation	17 (60.7)	208 (30.2)	36 (11.6)	45 (14.9)
Other symptoms				
Breathing**	2 (7.1)	20 (2.9)	4 (1.3)	5 (1.6)
Urination††	5 (17.9)	150 (21.8)	21 (6.8)	22 (7.3)
Fever‡‡	4 (14.3)	151 (21.9)	44 (14.2)	52 (17.2)
Hearing problem	0 (0)	20 (2.9)	9 (2.9)	5 (1.7)

* See Table 1.

† Excludes 45 cases that could not be classified and with untested melons.

‡ Not mutually exclusive from other classifications. ASO is a metabolite of aldicarb.

§ Values are given as number and percentage, which appear in parentheses.

Excessive salivation or sweating.

// Muscle weakness and/or twitching.

** Difficulty breathing or shortness of breath.

†† Excessive urination or incontinence. Was not included in case definition because of likelihood of urination associated with consumption of a large amount of watermelon.

‡‡ As noted by respondent.

cases and the other case groups, and therefore may be the least specific of the cholinesterase inhibitor symptoms. Fever was reported by 14.3% of those who consumed laboratory-positive melons and by 14% to 22% of those in the other groups. Fever was included to differentiate those persons with infectious illness (e.g., viral gastroenteritis), but it failed to do this (possibly because fever was self-reported). To screen for over-reporting, questions were asked about hearing problems; less than 3% of persons in any category reported same.

Several simpler case definitions were developed for illness that occurred within 2 h of watermelon consumption. The following symptom patterns were compared to the more complex case definition used for this outbreak: diarrhea only, nausea and/or vomiting only, diarrhea and nausea/vomiting, and diarrhea or nausea/vomiting. For the four definitions, sensitivity and specificity were calculated. Diarrhea or nausea/vomiting within 2 hr of watermelon consumption had the highest sensitivity (79%) and specificity (82%). Hence, if cases with ASO-positive melons had been classified on the basis of these two symptoms alone, 79% of the cases defined as "probable" using the complete definition would have been identified.

Cantaloupe-associated illness. In addition to the reports of watermelon-related illness, there were in this same period 77 illness reports associated with consumption of about 25 cantaloupes. Many of these cantaloupes were tested, and all tested negative for ASO. About half were tested for other pesticide residues (i.e., carbamates, organophosphates, and chlorinated pesticides); none were found. A few complaints about other types of fruit (e.g., honeydew melons) also were received, but none could be linked to any pesticides.

Discussion

Aldicarb is the most acutely toxic pesticide registered in the United States. It has two primary breakdown products: (1) ASO (for rats, $LD_{50} = 0.9$ mg/kg) and (2) AS (for rats, $LD_{50} = 24$ mg/kg).⁵ With well over 1 000 reports of probable pesticide illness from within and outside California, this episode ranks as the largest recorded North American outbreak of foodborne pesticide illness. In the past, intentional or inadvertent misapplication of aldicarb to cucumbers and mint was associated with similar, though more limited, outbreaks. The spectrum of illness reported in these outbreaks was similar to the current

one, ranging from mild to severe. No deaths have been reported from any of these food poisoning episodes.⁶⁻⁸ In these cases, as with the 1985 watermelon epidemic, identification of the epidemic was dependent on alert clinicians who quickly recognized the symptoms and signs of carbamate pesticide poisoning and on the abilities of laboratories to identify aldicarb metabolites (a test not routinely performed when testing for pesticide residues). Without careful surveillance, it would be easy to overlook such an epidemic because of the nonspecific nature of symptoms of early cholinesterase toxicity.

Aldicarb has been implicated in at least two deaths in agricultural workers.^{9,10} Although no deaths in this epidemic were attributable to A5O, the spectrum of clinical illness seen in this episode included many severely ill people. Some of the more serious symptoms and signs reported, such as marked bradycardia and hypotension, could have been lethal, particularly in the very young, the elderly, and the chronically ill. The prompt embargo and widespread publicity almost certainly were responsible for preventing a much larger epidemic and saving lives.

There are no known long-term or reproductive effects of aldicarb and its metabolites in the absence of maternal toxicity, and it is not a suspect carcinogen.^{5,11}

One would expect that there would be a certain number of people in the state who had gastrointestinal illness onset coincidentally within 2 h of eating melon; hence, some of the sporadic cases were reported through September. However, under-reporting at the beginning of the outbreak may have been substantial, given the long Fourth of July weekend and that the active surveillance system required 1 wk to implement fully. For example, the poison control centers were initially so overwhelmed with calls that they often did not have time to record complete reports; thus, many cases may have been lost to follow-up during the first week of the outbreak. However, a greater proportion of "probable" cases occurred after July 11; this suggests that a reporting bias in favor of minor coincidental illness may have occurred when the epidemic was first reported by the media.

It has been asserted that the entire epidemic was created by media coverage and reporting of illness coincidental with eating aldicarb-contaminated watermelons. However, the episode cannot be explained by coincidence. This is clear from the fact that those with laboratory-positive watermelons were likely to have a greater number of symptoms and more symptoms of severe acetyl cholinesterase inhibition than others.

A study of the geographic case distribution revealed no single retail source for contaminated melons, even when confined to cases confirmed with A5O-Positive tests in melons. This is probably due to the prevailing methods of distributing watermelons, which involve mixing unlabeled melons from numerous different sources. This results in marked intermingling during the distribution process. Any fu-

ture outbreaks of illness related to watermelon will likely be difficult to trace using epidemiological information alone. This certainly suggests a need for better labeling or tracking methods for watermelons.

There were many illnesses clinically compatible with carbamate poisoning but associated with aldicarb-negative melons. Although, as mentioned above, some of these could have been coincidental occurrences, it is also possible that the laboratory analysis could not detect A5O at levels that can cause illness. This issue has implications for the regulation of pesticide residues in foods and deserves further study.

An outbreak of this explosiveness and magnitude could never have been investigated and documented without the full support and participation of California's local health departments, emergency departments, and poison control centers. The workload generated by this event in these institutions and CDFA is hard to quantify. CDHS has time accounting records that suggest thousands of person hours were devoted by one agency alone. Since the 1985 epidemic, California has begun an integrated food surveillance program that involves local health and environmental health departments, CDFA, and CDHS. Monitoring for pesticide-related illness uses a report form similar to the one used for the 1985 outbreak, but with the simpler case definition for a probable case of carbamate poisoning of diarrhea or nausea/vomiting within 2 h of eating produce. This case definition is easier to use in the field and has sufficient sensitivity (79%) so that any future outbreaks of consequence should not be missed, even though it will overlook one of five individual illnesses.

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Management of this epidemic involved hundreds of individuals in government agencies at all levels and at numerous private institutions. The authors thank all of these persons. Special thanks go to Harvey F. Collins, Ph.D., for his editorial assistance, to Barbara Hopkins, David Epstein, and Martha Harnly, who assisted with data processing and analysis and illustrations; and to Carolyn Harris and Gette Meneses, who typed the manuscript.

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Dr. GOLDMAN. We will give you a full explanation of what we are proposing today, which is what we are proposing in the legislation.

Mr. ALLARD. Is there a scientific body out here that has recommended that you go ahead and say that all metabolites be given separate tolerances?

Dr. GOLDMAN. There is a major amount of science judgment involved in how this is done.

Mr. ALLARD. But the National Academy of Sciences or the National Toxicological Board haven't recommended that; have they?

Dr. GOLDMAN. They have, they certainly have. The National Academy of Sciences has, and a number of others have as well.

Mr. ALLARD. Would you provide the committee with those references so that we can look at those, please?

Dr. GOLDMAN. Sure. We also have recommendations from our own science advisory panel for the agency.

[The information follows:]

It is generally recognized by scientists that dietary risk assessments and residue monitoring must take metabolites into account, due to their potential toxicity as components of pesticide residues in food.

For example, in its 1993 report on Pesticides in the Diets of Infants and Children, the National Academy of Sciences (NAS) stated that "The residue testing program should include all toxic forms of the pesticide, for example, its metabolites and degradation products." (p. 10) In describing EPA's typical data requirements for active ingredients and metabolites, the NAS in 1987 noted that the required studies "reflect the need for data on all risks as well as those posed by residues in food." (Regulating Pesticides in Food: the Delaney Paradox, NAS, 1987 (p. 29)).

Within EPA's Office of Pesticide Programs' Health Effects Division (OPP/HED), an expert peer review group, the HED Metabolism Committee, makes the determination of how tolerances should "cover" metabolites, or whether separate tolerances should be established for specific metabolites that may pose risk concerns.

Mr. ALLARD. The new cancer standard that we talk about in H.R. 4362, on page 7, line 14, to page 8, then line 4, contains part of the Delaney clause. That is, it states: "That the cancer provisions apply to pesticides found to induce cancer in man or animals."

You have chosen to delete the part of the Delaney clause which states: "After tests which are appropriate for the evaluation of the safety for food additives." I find it interesting that you would delete the only portion of the Delaney clause which relates to recent scientific controversy surrounding appropriateness of high-dose testing, for example, the maximum-tolerated dose level.

Can you explain your thoughts on this?

Dr. GOLDMAN. Yes, if I can grab this here.

I think that you need to look at the rest of what we said here to understand what we are getting at.

First, we say: Inducing cancer determined on the basis of reliable scientific evidence, to pose a potential dietary risk in humans or animals.

We don't say as they said in the Delaney clause that it simply induces cancer in animals. We are insisting on a reliable body of scientific evidence.

I am having trouble finding the exact words.

Mr. ALLARD. But there is an issue of if it is reliable—I mean, we can talk about reliable facts, but is it appropriate in the regulatory—it is an important question.

Dr. GOLDMAN. We believe that we have provided language within the bill that allows our scientists to make these determinations about whether or not the evidence that has been presented is appropriate. And that also would allow us, if we have a situation, say, with some weird thing occurring just at the maximum-tolerated dose, or some weird mechanism that would not apply at a lower level, that we would be able to exercise our best scientific judgment in how we use those data.

We do not believe that what we have written here is, "son of Delaney," where there just is an "induces-cancer-in-animals finding" and we ignore the rest of the scientific evidence around that. That is not what we would want to do here.

Mr. ALLARD. On appropriateness, if we take that standard out, doesn't that create problems in our trying to work with the rest of the international community on harmonizing our test standards?

Mr. TAYLOR. I think it is important to keep in mind the conceptual breakthrough that this provision embodies and why the precise language is not as critical as it may have been in the Delaney clause as currently written.

Under Delaney clause, as you know, as currently written, the fact of carcinogenicity is dispositive. There is no opportunity for the agency to do a scientific safety evaluation. This bill is structured for the very purpose of allowing, requiring a careful, thoughtful scientific evaluation of safety.

The only reason we distinguish between the cancer endpoint as opposed to others, is because of a recognition that in many cases the only tool we have for evaluating the safety of a carcinogen is quantitative risk assessment, and we needed to introduce the concept of negligible risk. It is embedded in this provision, though,

that we have to use good, reliable scientific evidence and, obviously, appropriate studies is implicit in that.

Mr. ALLARD. Now let me interrupt you.

You talk about reliable. Is that the same—can we use that synonymously with validated? I mean, I see both terms kind of used interchangeably. I want to make sure we are talking about the same thing.

Dr. GOLDMAN. Yes.

Mr. ALLARD. So any time you use “validated,” it is the same thing as “reliable.”

Dr. GOLDMAN. The term “reliable” goes beyond that because you might use a method that was validated, but the way it was carried out, say, if they didn’t follow the standard of practice, the findings wouldn’t be reliable and wouldn’t be usable. And so what we are looking for are studies that have both been validated and were conducted properly and where the entire body of evidence that the scientists are looking at supports the finding.

As opposed to again in the Delaney approach—

Mr. ALLARD. So “reliable,” you have it applied to the test process itself; “validated” you are looking at the scientific literature to see if it tends to validate what you found and what you assumed to be a reliable test?

Dr. GOLDMAN. You might have a validated test that was performed in an unreliable manner, and you would reject, for example, so that the test is a valid test, but if it wasn’t done appropriately, we would want to reject.

Mr. ALLARD. So they are not necessarily synonymous.

Dr. GOLDMAN. “Reliable” encompasses “validated” along with other considerations that we have to make, when we review this data.

Mr. ALLARD. Mr. Chairman, I see my time is over. I would like to come back later, thank you.

Mr. STENHOLM. Mr. Glickman.

Mr. GLICKMAN. Thank you.

I think there are some things in all these bills that are useful. I would just make a couple of comments.

One, I have done a 180-degree turn on this issue of private rights of action. I think we have to be extraordinarily careful, by expanding the potential for unlimited litigation and bootstrapping, perhaps, unclear law that delegates a lot to a regulatory agency and in giving individuals the right to sue in an unlimited fashion based upon that unclear law.

So whether you sue for damages or whether you sue for equitable relief and how it is defined, I don’t think we ought to be rushed into a section which creates extraordinary opportunity for using the courts to solve problems that ought to be done by this body and by the regulatory agencies. That has been too often a procedure that we have done, and I think we have to be careful about it.

The second question I would have has to do with the tolerances. This tolerance, a reasonable certainty of no harm, is that in anywhere defined? It is?

Dr. GOLDMAN. Yes. The term “reasonable certainty of no harm” has been used in prior statutes. I am going to turn things over to Mike Taylor in a moment to expand on that in terms of its legal

sense. As a scientist, what that means to me, and as a risk manager, is that in the case of cancer, I can assure that there is a negligible risk. That in terms of noncancer effects, I can be pretty sure that nobody is going to be harmed, that there is going to be no chronic disease, no acute illness from that exposure.

As a scientist, I like the term also because it provides some flexibility for changes in science in the future, that unlike bright line standards and more prescriptive kinds of language that have been put into some of the laws that have been put forward in this and earlier Congresses, that we would not be creating a Delaney clause of the future, something that would lock us in to 1994 science, which we would not be able to use in 2004 or 2014.

Mr. GLICKMAN. Let me ask you this; if you were to be challenged in court as to a determination of whether—if somebody challenged your determination as to whether pesticide presented a reasonable certainty of harm or not, what legal standard would you use?

Would it be preponderance of the evidence, clear and convincing evidence? What is the legal standard that is used to protect your judgment or somebody could challenge your judgment?

Mr. TAYLOR. Let me make a couple of observations.

First, you should know that the “reasonable certainty of no harm” formulation was created by Congress in 1958 when it enacted the food additives amendment to the food and drug law and established for the first time the premarket approval, safety evaluation scheme for food additives. That was Congress’ very wise formulation of what safe should mean.

It is not an absolute concept, it is a science-based reasonable judgment sort of concept. And FDA has had over 30 years of experience making decisions and being challenged in court and defending those decisions.

I think the standard in the formal rulemaking provisions of the tolerance setting provision would be it is a court of appeals, substantial evidence on the record, as a whole sort of standard. I think I would want to get the lawyers to give you the precise language, but the question is whether the agency has considered all the relevant evidence and made a rational decision.

Mr. GLICKMAN. When you have two places—that occurs in rule-making, that also occurs when something is litigated in challenging the standards as well.

Now, the second part of your tolerance has to do with multiple tolerances at later stages of the food chain. How are you going to do that?

What are you saying, that fresh strawberries—get a pesticide on fresh strawberries basically is one area, but if the strawberries are frozen and they are packaged along with a fruit compote and sold in a grocery store, that is perhaps another tolerance?

Dr. GOLDMAN. We are trying to achieve two important policy goals. One is that we want to move toward a health-based standard for pesticide residues in food and a standard where we credibly are enforcing that health-based standard for what consumers actually eat.

But as we looked at our desire to do that, we realized that we still need to do enforcement at the farmgate. We still need to be able to, as early as possible in commerce, sample the food and

evaluate what the residues are and look at the potential for misuse.

And so what we realize is that in order to achieve both of those goals, because of the significant reductions that can occur in residue levels between the farmgate and the dinner plate, that we would in many cases, not all cases, but in many cases, we would need to have a dual system of tolerances in place.

Mr. GLICKMAN. But you would still have the definition "reasonable certainty of no harm" at all levels; right?

Dr. GOLDMAN. The definition of "reasonable certainty of no harm" would apply to the food as people eat it. And so we could, in the future, have, as we have today, farmgate tolerances, that if that were the level that consumers were exposed to, that we would not feel that we can ensure them a "reasonable certainty of no harm." But on the other hand, in the future, we would then have a backup of another tolerance that reflects what people actually eat that would be enforceable.

Mr. GLICKMAN. So you could make the judgment: Well, at this level this food would have a problem, but if processed, there wouldn't be a problem?

Dr. GOLDMAN. There wouldn't be a problem, a processor would not want a problem after washing and putting the food through the processes, even many fresh foods.

Mr. GLICKMAN. I just say that this does allow—I am not sure this is a bad idea or a good idea, but it could be a confusing idea in terms of how it is implemented. And it is just something we need to look at carefully.

I have one final comment. That is the integrated pest management issue. I think this is a provision of your bill, the administration bill. And I don't know if that is in the other bill or not. But I think this concept—

Mr. VOLKMER. Not to the extent.

Mr. GLICKMAN. Yes, I think this concept is very important. Farmers need to not only be penalized in this registration revocation and utilization of pesticides process, but there needs to be constructive and responsible alternatives and realistic alternatives, the way agriculture actually works to help them use a combination of pesticides or a combination of other pest-reducing procedures.

I want to go on record as being strongly supportive of at least the start of what you have made in this particular bill.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Farr.

Mr. FARR. Thank you, Mr. Chairman.

I would like to thank you, Mr. Chairman, for having this meeting. I think that of all the issues that are going on, without a doubt, health care is probably the most dominant, and wellness is part of that, and essentially the food chain is part of all that process and I can't think of a hearing that is more important to the American public than what is going on in this room right now.

I am very bullish about American farm policy and particularly our food safety policy. I want to compliment Dr. Goldman for making herself more accessible to farmers. I remember that she came from her vacation on a wet Saturday morning to meet with farmers in my district and had a good, lively discussion about where we are

headed. I think your proposal is a big improvement over existing law.

I have two questions that I would like to focus on. One is the issue that has been brought up here essentially that we find in specialty crops that I represent that the important crop protection tools are disappearing from the marketplace. We don't find adequate incentives for the chemical manufacturers to replace these products, so there is just not enough—in their terms—enough of a market to warrant the registration process.

I want to know what incentives you plan to propose to develop and register minor crop pesticides?

Mr. ELWORTH. We proposed a number of incentives and changes to make it easier to get new registrations and to keep the registrations that we have.

Mr. FARR. Will that bring the cost down so that—you make it easier, but is it going to be less costly? It is still a debate between whether it is worth the cost to register when the market is somewhat limited.

Mr. ELWORTH. In terms of the specific incentive, we have provided for an extended, exclusive use of data for both a major and minor use, when a registrant brings as many as three minor use registrations. That is a significant incentive for the registrant to put minor uses on the label.

Mr. FARR. I want to echo Mr. Ackerman's comment on IPM. Do you have a research and development program that will get safer pest control techniques to the farmer faster and sooner than the existing method than we are using? It seems that there needs to be a lot more education to help the farmer implement IPM.

Mr. ELWORTH. We made a specific effort in the last 2 months to put together a strategic plan for integrated pest management implementation for fiscal year 1996 that focuses specifically on research and extension programs and what they will deliver to the farms. So we will evaluate them in terms of what they deliver to producers that they can use, not simply the funding level.

In addition, we are proposing and hope to put into the budget a program specifically for research into alternatives for pesticides that producers are losing because of regulatory action.

Mr. FARR. You don't have the money for that this year? You are going to be asking for it next year?

Mr. ELWORTH. We will be putting together a budget proposal that will include that. We recognize how tough the Federal budget is. This is a priority for the Department which we intend to pursue, we hope, with the help of Congress.

Mr. FARR. We would be very interested in that. Some of us on this committee would be pleased to work with you on that.

Last, in my area, the largest strawberry growing area in the Nation, methyl bromide is a critical pesticide for farmers and we understand it is going to be phased out by the year 2001. I believe there was an additional \$5 million that had been requested by the administration for research, but didn't get through committee so we face this again, a critical situation for the methyl bromide users.

According to the information I have, the EPA and the USDA are allocating funds to create entirely new research projects instead of

supporting ongoing efforts at educational institutions and projects which have been in the works for some time.

I would appreciate you looking into supporting the ongoing efforts rather than investing in a lot of new efforts. I would like to hear back from you on how you are going to plan to spend the research funds available and how much will be going toward funding of ongoing efforts in the field.

Mr. ELWORTH. Given the specific, the very short period of time we have in which to put together alternatives, we have set in place a process in which to meet with the growers who depend on these to make sure that the research will result in something that in time will actually take place.

We are supporting a conference, and the Deputy Secretary has met with growers to make sure that our research efforts take advantage of all of the work that had been done and is going on.

If there are any questions that your producers have, we welcome meeting with them directly. I would be glad to respond to you directly as well.

Mr. FARR. I am curious as we look at the Delaney clause and revisiting it, in an era when we can measure one part per quintillion what was the standard at the time the Delaney clause was developed? Do you know what our measuring capabilities were?

Dr. GOLDMAN. At best, in the range of a few hundred parts per million at that time, no more. It certainly was not the capability that we have today to get down to parts per quadrillion and so forth.

Mr. FARR. So technology plays a major role in our decisionmaking today.

Thank you very much, Mr. Chairman.

Mr. STENHOLM. Ms. McKinney.

Ms. MCKINNEY. Thank you, Mr. Chairman. I have a prepared statement that I would like to submit for the record.

Mr. STENHOLM. Without objection, your prepared statement will appear in the hearing record.

Ms. MCKINNEY. I have only one question. I was recently visited by some of my peanut farmers and they told me that there is a specific pesticide that they cannot use, but that still enters this country because peanut producers around the world use it and we import that product with that chemical on it.

Is that something that is a legislation loophole that your bill would help close or is that an enforcement loophole?

Dr. GOLDMAN. Well, two things; one is that if there is not a tolerance on the books in this country, then the residues should not be present on any imports coming into this country, and I would be interested in hearing about what the specific pesticide is and we can work with the FDA on whether or not we can monitor it.

One of the things that we have been concerned about, and with our circle of poison provisions, is that in cases where pesticides are exported from this country and then can come back on food, today there is not a requirement that the company provide an analytical method to the FDA.

One of the things that we certainly want to make sure of is whether this is something that would be routinely picked up in the analyses and if not, why?

This is the kind of issue that we would have to explore to see if it was a regulatory problem or enforcement problem or what.

Ms. MCKINNEY. I would enjoy working with you on that. Please check, and I also have some written questions.

Thank you, Mr. Chairman.

[The information follows:]

Following the June 15 hearing, EPA learned that the specific pesticide Congresswoman McKinney was referring to is the fungicide tebuconazole. As of the date of the hearing, EPA was in the process of evaluating data that had been submitted in support of a registration application and tolerance petition for tebuconazole for use on peanuts. On July 15, EPA concluded its review of the data and determined that use of this pesticide on peanuts, consistent with EPA-approved labeling, met the standards for approving the registration and tolerances. Therefore, EPA granted a registration for tebuconazole for use on peanuts and established tolerances for residues on peanuts and peanut hulls. This decision took effect July 15 and will be published in the Federal Register in the near future. Thus, the pesticide may now be used by U.S. growers, and residues in compliance with the established tolerances are permitted.

EPA's tolerance regulations apply equally to domestically produced and imported foods. No food, whether domestically produced or imported, may legally contain residues of a pesticide unless EPA has granted either a tolerance or an exemption from the requirement for a tolerance with respect to the specific food. The Food and Drug Administration (FDA) is charged with monitoring the food supply and enforcing these requirements for most food products in interstate commerce, including peanuts. Therefore, peanuts or any other foods that contained residues of tebuconazole prior to the issuance of the tolerances would have been subject to enforcement action by FDA.

Residues complying with the recently issued tolerances are now permitted. Residues of tebuconazole found on any commodity other than peanuts or peanut hulls would constitute a violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). Moreover, peanuts or peanut hulls found to contain residues of tebuconazole in excess of the tolerance EPA has established (0.1 parts per million/peanuts and 4.0 parts per million/peanut hulls) would also be considered adulterated foods and would not be allowed into the channels of trade. FDA has been provided with an analytical method for testing for tebuconazole residues.

The Administration's legislative proposals would place new restrictions on the exports of pesticides that have not been approved for use in the U.S., including among other provisions a prohibition on the export of any pesticide banned in this country due to health concerns and a new requirement that an analytical methodology be supplied before any unregistered food use pesticide may be exported. While we recognize that many pesticides exported from the U.S. may also be produced in other countries, these new requirements will help ensure that pesticides exported from the U.S. do not come back to this country as illegal residues on imported foods.

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Questions:

*Department Operations and Nutrition Subcommittee
Hearing on Administration's Pesticide Reform Proposal
June 15, 1994
Questions for Clinton Administration Panel*

1. EPA has recently released a list of pesticide tolerances subject to revocation under the Delaney clause. What is EPA's schedule for enforcing the Delaney clause and revoking these tolerances?

2. The Administration proposal provides a new phase down/phase out authority under FIFRA.

Can you name one pesticide that exceeds the risk standard proposed in the Administration bill that would be phased out under this authority?

Can you name any pesticides that pose unacceptable risks to children?

3. The Administration proposal states that the Administrator "shall fully account for available information" on food consumption and the cumulative effects of pesticides, and "shall fully account for valid scientific information" regarding other health effects.

What occurs if there is no available information?

What will be the agency's presumption in the absence of relevant information on consumption patterns for children, and the health effects of pesticides?

4. A 1992 EPA memo from former Assistant Administrator Linda Fisher to Representative Charlie Rose of North Carolina listed several pesticide tolerances which violate the one-in-a-million negligible risk standard at the tolerance.

What would happen to these tolerances under the Administration bill?

Within thirty days, please provide us with an estimation of what these tolerances would be under the provisions of the Administration package designed to protect infants and children.

Within thirty days, please provide us with an estimation of how much these tolerances would need to be reduced to accommodate a reasonable certainty of no harm standard.

How would tolerances be lowered under this proposal ?

How would the new tolerance be enforced?



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CONGRESSIONAL
AND LEGISLATIVE AFFAIRS

July 26, 1994

Honorable Cynthia Ann McKinney
Subcommittee on Department Operations and Nutrition
Committee on Agriculture
United States House of Representatives
Washington, D.C. 20515

Dear Representative McKinney:

Enclosed are the U.S. Environmental Protection Agency's responses to questions arising from the June 15, 1994, hearing on the Administration's pesticide safety legislation. These responses were prepared by EPA's Office of Prevention, Pesticides, and Toxic Substances.

If we can provide further assistance, your staff is welcome to contact Robert Coronado ((202) 260-5431).

Sincerely yours,

A handwritten signature in cursive script that reads "Christopher P. Hoff".

Christopher P. Hoff
Deputy Director
Legislative Analysis Division

Enclosure

cc: Honorable Charles W. Stenholm
Chairman
Subcommittee on Department Operations and Nutrition
Committee on Agriculture

U.S. ENVIRONMENTAL PROTECTION AGENCY'S ANSWERS TO
 REPRESENTATIVE CYNTHIA ANN MCKINNEY'S QUESTIONS
 FROM JUNE 15, 1994 HEARING
 SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
 U.S. HOUSE OF REPRESENTATIVES

1. EPA has recently released a list of pesticide tolerances subject to revocation under the Delaney clause. What is EPA's schedule for enforcing the Delaney clause and revoking these tolerances?
- A. EPA is continuing to move forward to implement the Ninth Circuit U.S. Court of Appeals' decision in the Les v. Reilly case. That case held that the Delaney clause of the FFDCA must be applied strictly. EPA has now finalized revocations of the food additive regulations of the pesticides directly involved in the litigation. In addition, we have implemented policies to revoke or deny emergency exemption requests and to defer processing of new applications for pesticide uses that appear to be subject to the Delaney clause.

The next step is to review and take action on pesticides that appear to be subject to the Delaney clause but were not specifically targeted in the court case. On June 30, 1994, EPA proposed to revoke 26 food additive tolerances involving 7 such pesticide chemicals. Similar proposals for a number of other chemicals are planned for later this summer and fall. In the near future, EPA also expects to begin making decisions on several key policy issues raised in connection with the implementation of the court's interpretation of the Delaney clause, including the issues raised in a petition from the National Food Processors Association and comments received on that petition.

2. The Administration proposal provides a new phase down/phase out authority under FIFRA.
 - a. Can you name one pesticide that exceeds the risk standard proposed in the Administration bill that would be phased out under this authority?
 - b. Can you name any pesticides that pose unacceptable risks to children?
- A. a. We believe phase-out/phase-down authority can be an important tool in achieving prompt risk reduction and data submission whenever there is credible scientific evidence that a pesticide is reasonably likely to pose a significant risk to health or the environment. While work to resolve scientific uncertainties goes on, this authority will enable EPA to begin to reduce exposure. This authority will also strengthen the agency's hand in negotiating voluntary risk

reduction strategies and create incentives for resolving uncertainties expeditiously.

One example where the agency might have used this authority is the case of the termiticide uses of chlordane. In 1978, most uses of this pesticide were canceled, but the termiticide uses remained registered because of questions about the lack of adequate alternatives and because it appeared at that time that exposure from these uses was minimal. In the 1980's, however, EPA began to question this exposure conclusion and required indoor air monitoring data to ascertain whether there was a risk that justified cancellation. With phase-out/phase-down authority, EPA could have begun to limit use and exposure while the monitoring data needed to resolve our concerns about exposure were being developed, instead of waiting for the data to be developed and reviewed.

When the data were submitted, they did show significant exposure. The final decision to cancel termiticide uses of chlordane was made in 1987. If EPA had phase-out authority, the public's exposure to chlordane could have been reduced years earlier, while data gathering was ongoing.

b. If EPA had data showing that a pesticide posed unreasonable risks to children, we would move immediately to reduce or eliminate those risks using the tools currently available to us. For example, when reports of higher than anticipated residues of aldicarb in individual bananas suggested that there could be a risk of illness to young children with high dietary consumption of bananas, EPA immediately called in health officials, the pesticide manufacturer and the banana producing industry to review the potential risk and assess options for action. The result was prompt voluntary suspension of all aldicarb use on bananas.

Although the aldicarb example is a positive one, EPA cannot always count on prompt voluntary action. Therefore, the Administration is proposing to provide EPA with additional regulatory tools and streamlined procedures that will enable EPA to take prompt, effective action to address risks when they are identified in the future. In addition, we propose to get better information on pesticides in the diets of infants and children, as recommended by the National Academy of Sciences in its 1993 report.

With respect to existing pesticide residue tolerances, EPA is developing a list of tolerances which, based on worst-case assumptions about residue levels and exposure, appear not to meet the health-based standard proposed in the new legislation. The list will include pesticides that appear

to exceed the one-in-a million risk benchmark for carcinogens, or that exceed the Reference Doses/Acceptable Daily Intakes established by EPA. Under the Administration's legislative proposal, these pesticides would be targeted for fast-track, priority review to ensure that they meet the new standard within 3-4 years of enactment, or the tolerances would be revoked.

3. The Administration proposal states that the Administrator "shall fully account for available information: on food consumption and the cumulative effects of pesticides," and "shall fully account for valid scientific information" regarding other health effects.

What occurs if there is no available information?

What will be the agency's presumption in the absence of relevant information on consumption patterns for children, and the health effects of pesticides?

- A. If EPA determines that the available information is inadequate to make the required safety findings, the Agency may either require that data be developed to resolve the uncertainties or deny the registration and/or tolerance.

The Administration's proposals require a review of all existing pesticide tolerances within seven years of enactment. The standards for tolerance-setting also require the use of an additional uncertainty or "safety" factor and other appropriate measures to ensure that children are fully protected. EPA's judgments will be made on a case-by-case basis, taking into consideration the data base on each pesticide and current scientific understanding at the time of the decision. We will always have some data on exposure and health effects, and we will upgrade the data base as our understanding advances in the future. The burden is on the tolerance sponsor (in most cases, the pesticide manufacturer) to show that the statutory standards are met. If EPA concludes that the data submitted in support of a pesticide is insufficient to make the required safety findings, tolerances will be revoked as they come up for review and new tolerances will not be established.

4. A 1992 EPA memo from former Assistant Administrator Linda Fisher to Representative Charlie Rose of North Carolina listed several pesticide tolerances which violate the one-in-a million negligible risk standard at the tolerance.

- a. What would happen to these tolerances under the Administration bill?

Within thirty days, please provide us with an estimation of what these tolerances would be under the provisions of the Administration package designed to protect infants and children.

Within thirty days, please provide us with an estimation of how much these tolerances would need to be reduced to accommodate reasonable certainty of no harm standard.

- b. How would tolerances be lowered under this proposal?
- c. How would the new tolerance be enforced?

- A. a. As described in the response to Question 2, EPA is developing an updated list of pesticides that appear not to meet the health-based standard proposed in the Administration's bill, including pesticides that appear to exceed the one-in-a million benchmark for carcinogens and pesticides that exceed the Reference Dose/Acceptable Daily Intake established by EPA. Under the proposed legislation, these tolerances would be reviewed on a "fast-track;" 75% of the reviews would be completed within three years of enactment and 100% would be completed within four years.

It is not possible to produce reliable predictions on the outcome of the tolerance reviews, since we expect to receive additional data and information during the review period that could result in revision of the risk estimates. For example, in preparing the list of potentially affected pesticides, EPA is assuming that 100% of crops are treated with the pesticide and that residues are always present at the tolerance levels. These assumptions tend to overstate exposure, and thus risk.

It has been EPA's experience that when information on the percent of crop actually treated and data on residue levels closer to the point of consumption are factored in to the dietary risk assessment, the estimated risk is substantially reduced. In many cases, risks which were estimated to be above negligible levels are found to be below the negligible risk standard when more refined estimates of actual residue occurrence are used. When the information is available, it often reduces the estimated risk very substantially. Thus, to the extent that such additional data resolve risk concerns, it may not be necessary to revise tolerances. Similarly, better data on the health endpoints of concern could enable EPA to better define the potential risks and result in substantially lower estimates.

- b. If, after evaluating all available data during the tolerance review period, EPA concludes that the risks still

exceed the standard of "reasonable certainty of no harm" or "negligible risk," a number of options to reduce risks are possible. Tolerance levels could be lowered as a result of changes in application rates and directions for use. Some uses could be dropped, to bring the overall risk of the pesticide residue down to negligible levels. Separate tolerances could be established for residues at the farmgate and residues closer to the point of consumption (e.g. tolerance limits that would apply at the "supermarket" or retail level). If none of these approaches achieves the necessary risk reduction, EPA could revoke the tolerances.

The mechanisms for establishing, modifying and revoking tolerances are set out in the Administration's proposal, and involve basic notice-and-comment procedures, subject to judicial review.

c. FDA would continue to be responsible for conducting monitoring programs, sampling foods and enforcing the tolerances for food products subject to its authority (which covers most foods), and USDA would continue to enforce tolerances for meat, poultry and some egg products. If multiple tolerances exist for the same pesticide on a commodity at different points in the chain of production and distribution (e.g. farmgate and supermarket), the tolerance applicable to the point where the sample was taken would be enforced.

Among the important features of the Administration's proposals are the enhanced powers that would be provided to FDA to conduct its enforcement programs, including civil penalties, recall, and embargo authorities. These provisions will improve FDA's ability to deter violations of pesticide residue standards and prevent violative foods from reaching consumers.

Mr. STENHOLM. Ms. Lambert.

Ms. LAMBERT. Thank you, Mr. Chairman, and a special thanks to you for certainly bringing up this issue.

I am not a FIFRA veteran as many of those around here are. I have to say that my frustration over the length of time that it has taken us to get to this point has been great.

One of the problems I think that we see with the current Delaney clause is the discrepancy that a raw product that complies with a section 408 tolerance may be a violation under the law of the section 409, and it is my understanding that under the administration's proposal here today that a single negligible risk standard is established for both raw and processed commodities, but also EPA is given the authority to establish separate tolerances for food at the time of harvest and at the time of retail, and after processing.

So you really don't have a single standard, in essence, there are three standards there at least. What was the reasoning behind this proposal if we were trying to consolidate and yet we have expanded? And doesn't that really mirror the problem that we currently have?

Dr. GOLDMAN. It is a different issue than the Delaney issue. The Delaney issue is that we would treat a grape different than we would treat a raisin, even though that grape or raisin might be on the dinner plate that you are eating. What we are looking at is that we want to respond to the criticism that we don't enforce a health-based standard.

We want to make sure that the food that is on your dinner plate, the tolerances on those foods reflect a safety standard, but in doing that, we don't want to break something that currently works pretty well which is being able to do enforcement right at the farmgate.

We know that there are often great reductions in the levels of pesticide between the farmgate and the dinner plate. If we took that dinner plate standard and applied it at the farmgate, then we might not be able to allow a perfectly reasonable use of a pesticide to meet the needs of the farmers.

We believe that we need to move to being able to have this kind of flexibility where when needed we can have dual tolerance. It would not be required. It would just be utilized when we need to use it.

Ms. LAMBERT. Who would determine the need?

Dr. GOLDMAN. Basically the need would be determined by the scientific data. The way the farmgate tolerance would be set is the way it is set today, which is taking the best agricultural practice and looking at the residue levels that result from that.

If that number is above a health-based standard, which today is something like 15 percent of tolerances are above a health-based standard, then we would be required to not just go through the calculations that we do, because we certainly attempt to look at that and make sure that the actual residue levels are below a health-based standard, but we also would be required to set a tolerance that would allow us to enforce that standard so that the consumers could be absolutely certain they are being protected there.

What we have been criticized for is that although we go through the calculations showing that the levels are lower on the dinner

plate, we don't have an enforcement scheme that can guarantee that to the public, and we feel that we should be able to do that.

Ms. LAMBERT. So you really would be expanding it to three standard levels then?

Dr. GOLDMAN. There would be one standard in terms of a health-based standard for the residue levels on food, but there would be potential for enforcement to occur in more than one place. Currently we only enforce at the farmgate. What we are proposing is that we be able to have enforcement at the supermarket level as well.

But we would make sure that that food in the supermarket meets one standard, which would be a health-based standard.

Ms. LAMBERT. So, if I am reading this correctly, not only at the retail, but also at the processing so if you are going to take that grape and not just make a raisin, but you are going to make grape juice or grape jelly, you are going to utilize that outlet for another area where you are going to do—

Dr. GOLDMAN. Only if the circumstances require it. Where we are at the farmgate, we have a tolerance that is above a health-based standard only if it is required. What we are really looking for here is the flexibility so that we can meet both of these sets of needs and we certainly don't want to throw out the baby with the bath water in terms of best farms practices by moving to a health-based, tolerance-based system.

Ms. LAMBERT. I am glad to see that the administration is concerned with the health of our children. I have recently introduced legislation in the health care arena for children. In this committee we have taken a tremendous look at nutrition, which I think is important in all aspects of children's lives.

Would you please explain in practical terms how you plan to go about setting the separate tolerances for children as opposed to adults?

Dr. GOLDMAN. There would not be a separate tolerance for children, but what we would be required to do is set the tolerance to protect the most vulnerable in the population. If children are the most exposed and the most susceptible and you need to set a stricter standard to protect them, that would be the standard that we would all be covered by.

Ms. LAMBERT. Are you going to take into account that children have certain foods in their diet which are more prevalent and in larger quantities?

Dr. GOLDMAN. It looks at the specific risks that they have and the other is exposure, the unique dietary patterns that children have that all parents know about and we want to take both into account.

Ms. LAMBERT. One last question on the cost. You mentioned the increase of \$15 to \$20 million additional. You seemed very confident that that would have no impact on supply, affordability, safe supply of food in our Nation, and yet some of the other battles that we fight in this committee are looking at the cuts in the annual ag budget which is less than 1 percent of the annual budget in this Nation.

We are asked continually to take an enormous percentage from USDA and other areas. Subsidies are always a big bone of conten-

tion and then when we look at the possibility of paying for GATT, that obviously is an issue that has been tender in the ag area.

So if you look at what the cost might be, coupled with other costs—I come from a seventh-generation farm family and it is much more difficult now and much more costly to produce a crop for the price of what we are getting for our commodities.

Dr. GOLDMAN. These are all good points and I think we realize working within the administration how limited resources are today, and it is why we have asked to fund this activity using fees rather than by using general revenues.

To put it into perspective, I think it is important to think about a couple of things. One is that we have some 1 billion pounds or so of pesticides that are produced in this country every year. It amounts to something like \$5 billion or \$6 billion in sales. There is a lot of money involved here.

The second is in terms of input of pesticides in agriculture. It is a very important cost for the agricultural producers, but if you look at a loaf of bread, the amount of money that you are paying for that loaf of bread that goes for the pesticides is less than a nickel. It is a small amount of the total amount that goes into it. We think that when you look at it—

Ms. LAMBERT. But it is hard to make the loaf of bread without the wheat. Granted it is a minimal part of the cost of it, but it is a critical element.

Dr. GOLDMAN. It is a critical element, but at the same time when you look at it in perspective with the overall market for pesticides and the overall inputs of these into food, to achieve this extra measure of safety, we think that it is worthwhile.

I mean, obviously that is something for Congress to decide, but we propose that it is worthwhile.

Ms. LAMBERT. Thank you for your willingness to be here and to work with us.

Thank you, Mr. Chairman.

Mr. STENHOLM. I want to follow up on your last statement, Dr. Goldman: That is something for Congress to decide, and I think that is why we are here today.

I want to reiterate, it is my intention to get a bill out of this subcommittee that you will support and that will achieve the goals which you have stated, each of you this morning, the goals of the administration.

We are going to move as expeditiously as possible. Even though we have started rather late in the year, we still have time, provided all of the parties want a bill.

I want a bill. I believe you want a bill. Therefore we are going to move quickly in this committee to put together a bill that you will support or that you will not oppose; whichever way—those are the two ideals.

Along that line, I think it is very critical now that we ascertain the views of those of you at the table in one area, and that is as you state on page 19: "The statute would specify factors EPA should consider in assessing pesticide risks as part of the tolerance-setting process, including, for example, risks to significant subpopulations, risks from multiple sources of exposure, in addition to

food, and risks from pesticides that have a common mechanism of action."

This comes under the general heading for standards for tolerance setting. I do not mean to leave out anything or everything, but the whole question of setting tolerances, as Mr. Allard and others have talked to, is critical. In doing this, I think that it is very important to ascertain what—I hate to use the word facts, but from my limited vocabulary, that is the best way to do it.

You correct me if my understanding is wrong, and for sake of narrowing discussion, let's speak in terms of carcinogens, admitting that there are other food safety health concerns other than carcinogens, but let's speak in terms of carcinogens.

It is my understanding that 98.5 percent of the known carcinogens in the world are naturally occurring. What is your percentage?

Dr. GOLDMAN. I have never seen a statistic on that.

Mr. STENHOLM. Is 98.5 percent reasonable?

Dr. GOLDMAN. No, it does not sound correct to me. That sounds like an enormous overestimate, but I would not presume to say that we know what all the naturally occurring carcinogens are either, but it sounds like a great overestimate.

Mr. STENHOLM. Good point.

Would we be able to agree that the overwhelming majority of the known carcinogens today are naturally occurring and not man-made?

Dr. GOLDMAN. I would not agree with that, no.

Mr. STENHOLM. You would not agree with that.

Mr. Taylor.

Mr. TAYLOR. I don't have the numbers, Mr. Chairman, but—

Mr. STENHOLM. I am not concerned so much about the numbers as I am in ascertaining the beliefs of those of you at the table regarding carcinogens and the general attitude of man-made versus God-made.

Mr. TAYLOR. If you are being very careful in saying known human carcinogens, which means that we have done testing and actually know something, I agree with Dr. Goldman that we have many more synthetic manmade chemicals that fall in that category because we tend to test those. We don't tend to test things that occur in nature.

Mr. STENHOLM. Have we tested any naturally occurring carcinogens?

Dr. GOLDMAN. We have, and there are a lot of data on a couple of them, especially aflatoxins.

Mr. STENHOLM. Then let's confine ourselves to that which we know. If we take a naturally occurring carcinogen and subject it to the registration process that we are subjecting pesticides to, do we get different results, specifically?

Dr. GOLDMAN. For aflatoxins, specifically, actually, we would apply a very stringent standard. In fact, I believe we do apply a very stringent standard under other parts of our law for the finding of aflatoxins as contaminants in food and that we do quite stringently try to control aflatoxin's presence in food.

Mr. STENHOLM. If we subject mice to the maximum-tolerated dose of naturally occurring carcinogens and let's talk about aflatoxins, do we get similar results in the test?

Dr. GOLDMAN. When we test mice with aflatoxins, we do find that cancers develop in the mice, not just at the maximum-tolerated dose, but also at lower doses. One of the issues about maximum-tolerated dose, I think most people believe that you have to do some kind of a high-dose test. The question is where do you set that dose?

Mr. STENHOLM. Precisely. What I am trying to get at is if we subject the naturally occurring carcinogens to the same rigorous testing that we do others, do we or do we not get similar results?

Dr. GOLDMAN. Certainly for aflatoxins, we do.

Mr. STENHOLM. In your specific knowledge, would you have any reason to believe that if we took any other naturally occurring carcinogen and subjected it to the same rigorous test that we subject man-made, should we be expected to get different results?

Dr. GOLDMAN. I think by definition, if it is a carcinogen, we should expect to see in a test, at least a test system, that you would see cancers produced. Otherwise, you couldn't define it, kind of in a way that we decide if something is a carcinogen by definition, I think the answer is yes.

Mr. STENHOLM. The answer would be yes. Then, in the GAO study of May 1994, "Pesticides: Options to Achieve a Single Regulatory Standard," I want to read: "The administrative policies that EPA developed to reconcile differences in the Federal pesticide laws have been and may again be challenged in court. If these laws remain unchanged, and if EPA retains the coordination policy and other remaining policies, that decision may compel the revocation of tolerances for a large number of pesticide uses.

If the laws remain unchanged and if EPA revokes its remaining policies, fewer tolerance would have to be revoked. Amending the Federal pesticide laws to establish a single standard for regulating pesticide residues in or on all foods would give EPA a coherent basis for setting tolerances and would allay controversy over the agency's implementation of the pesticide laws.

What that standard should be, how much risk it should allow, and whether it should permit the consideration of benefits is a question that science cannot yet answer definitively."

Now that is the part I would normally have read, but it would have been taken out of context the total paragraph, including the final summation. Although scientists have improved their ability to detect pesticide residues and assess risk, they cannot determine exactly how much risk these residues pose either alone or in combination with other environmental effects.

Therefore, at this time, decisions about whether to allow residues of carcinogenic pesticides in food are ultimately policy judgments; judgments that the Congress may be called upon to make in reauthorizing FIFRA and amending FFDCA.

A clear resolution of the differences in the Federal pesticide laws would help to avoid recurring regulatory difficulties and disputes.

Now, that is the challenge for this committee. As Mr. Glickman pointed out a moment ago, the tendency for some is to have an absolute standard for pesticides, but to completely ignore the fact

that we could ban all pesticides and we may not do one thing for consumers, whether they be children or anything else.

I ask the question again, is there anyone here from the tabloid TV at this moment that has heard this wonderful dissertation by the chairman? The answer is no. The point here is that as we roll up our sleeves and go to work on this, we are going to have to somehow get the general public's attention and that means that many of the witnesses today are going to have to be willing to participate in a common sense way to resolving these questions.

If we remain at loggerheads, we are going to have some real problems that deal with food production. What I am trying to remind people of, over and over and over again, is that consumers and producers have mutual interests. Particularly if you are concerned about hunger and nutrition, you have a mutual interest in seeing that we maintain a productive agriculture. Not only in the United States, but that we allow other countries to benefit from the tremendous technology that we have, in fact, been able to achieve in this country.

As Mr. Volkmer pointed out a moment ago, we are in danger by misguided individuals who choose to use only those portion of studies. We are in danger of doing some real harm to technological advances. For other people in the world, the 800 million people that go to bed hungry every night, could very well be denied the opportunity to feed themselves if we are not careful how we do this.

Therefore, I repeat, it is my intention to see that we not separate the Delaney clause from FIFRA; that we work together to achieve something that the administration, and as you have mentioned, our response to those concerned about this, that we can have coherent responses that will be acceptable to the overwhelming majority of the American people, not to those who have more limited views, but to recognize science cannot give us the ultimate answers and set an ultimate standard; we cannot do that.

Therefore, why would we expect it? It has to be a judgment, and the judgment has to be one in which we all agree will give us a safe food supply.

I may have additional questions that I will submit for the record. I apologize to my colleagues for taking more than my 5 minutes, but this to me is the fundamental question that is going to govern the way this committee is going to function, and I expect based on what you have said, you intend to work with this committee in resolving it and at least a paraphrasing way of which I have stated these fundamental differences today.

Dr. GOLDMAN. One thing I would like to say in response to that is that the administration is in full agreement with your sentiment that these two bills should not move forward independently or separately. One of the reasons why we worked on revising them together is that we think that part of what is broken today is the conflict in standards and operations between the two.

We believe that both of these must move forward, not just one independently of the other. So we are in full agreement with you on that.

Mr. STENHOLM. Great. I just wanted to be sure that nobody thought that the chairman came in on a turnip truck and then recognized the dangers of keeping them separate from the standpoint

of achieving the goals. I appreciate that and we look forward to working with you.

Mr. Smith.

Mr. SMITH of Oregon. Mr. Chairman, you are doing pretty well. If you need another 5 minutes, just get on with it.

Mr. STENHOLM. We have had all the speeches that we can stand this morning.

Mr. SMITH of Oregon. Following your line of questioning, and pointing out that this is going to be a judgment call, we cannot rely upon science to give us the directions and of course that is always dangerous, but in relation to that issue, the administration's bill has left out any definite consideration, except transitional provisions for existing tolerances.

In 10 years of enactment, H.R. 4362 would eliminate tolerances for food use pesticides. This phaseout, coupled with the provisions that subordinate FIFRA to FFDCA means the elimination of FIFRA's ability to evaluate risk versus benefits in the future.

I think everybody agrees that benefit consideration should focus on factors affecting consumers, workers, and the environment and production agriculture. So my question is: Why does the administration propose eliminating considerations of benefits for food use pesticides to offset even the tiniest risk?

Dr. GOLDMAN. What we are basically looking at is not an offset of benefits with tiny risk. What we are looking at is the policy position that we have taken that we ought to be able to assure a reasonable certainty of no harm to the consumers for pesticide residues on food. That food should be safe, and that we should not trade off safety of the food supply for narrow economic considerations or other kinds of narrow considerations.

We have not taken a position that the benefits risks trade-offs in FFDCA should overrule FIFRA, because in FIFRA, and the risk-benefit balancing, there would continue to be lots of balancing having to do with the other risks that we must address; the risks to farmworkers; the risks to the environment; and the risks to ground water. But we do feel that when it comes to the safety of the food supply, especially for our children, that we need to make public health protection paramount.

Mr. SMITH of Oregon. But you do do this for food use pesticides, you admit?

Dr. GOLDMAN. For food use pesticides and with an adequate period of time to make a reasonable transition.

Mr. SMITH of Oregon. Let me follow up with an example here. You talked about aflatoxin. We know that natural plant molds and fungi produce toxins that are dangerous to people. They kill people. They are cancerous. They are carcinogens.

For instance, one of the best known ones is aflatoxin. Under your proposal, if a pesticide was introduced that was only marginally above risk standards, but produced real human health protection that far outweighs the risk posed by the pesticides, the EPA would deny that pesticide and, in fact, eliminate the opportunity to improve human health and eliminate aflatoxin. How do you answer that question?

Dr. GOLDMAN. Well, we would be willing to work with the committee to craft a provision to take care of that kind of a trade-off

for public health concerns. Our basic premise here is that food must be safe. I certainly don't want to end up on tabloid TV explaining to people why we can't guarantee that our food supply is safe.

Mr. SMITH of Oregon. See that is the problem. I understand that it would be nice to have this in a nice tidy package for FDA and EPA to say we have eliminated the possibility that we are going to authorize any pesticide or herbicide that is in any way dangerous to human beings.

You can't do that and we can't do that. We all agree with that. But the judgment call here is an important one. It would relieve you, I understand, of a lot of liability. You could sit and say "I am above reproach. I have done it perfectly. I am on record and if somebody else has a problem, forget it, but we can't do that, can we?"

Dr. GOLDMAN. We are not asking to do that. The standard that we are proposing, the standard of the reasonable certainty of no harm, it is not an absolute guarantee of zero risk. It is a standard of a reasonable certainty that nobody is going to be harmed, which is what we think is something that the Government can provide for the public.

We can't provide the perfect world with zero risk.

Mr. SMITH of Oregon. Would you send me a definition of what you believe that is? I don't know that there is a definition in law. I understand that it is a review of case law that Mr. Taylor has explained to us over the years in the FDA. That standard was used.

I would like to see a definition or at least try to give me a definition of that test.

Mr. TAYLOR. Be happy to provide that.

Mr. SMITH of Oregon. I thank you.

[The information follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The "Reasonable Certainty of No Harm" Standard

The "reasonable certainty of no harm" standard stems from the legislative history of the Food Additives Amendment of 1958 [P.L. 85-929]. In the report of the Committee on Interstate and Foreign Commerce, which amended and favorably reported H.R. 13254, the Committee stated:

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not--and cannot--require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

In determining the "safety" of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related substances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.

Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.

The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the specific additive in question, among others, the following relevant factors: (1) the probable consumption of the additive and of any substance formed in or on food because of the use of such additive; (2) the cumulative

effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and (3) safety factors which qualified experts consider appropriate for the use of animal experimentation data...

The Senate Committee on Labor and Public Welfare repeated this language almost verbatim in its report on the 1958 amendment.

The Senate report also stated:

Conscious of the fact that any substance or, for that matter, any particular food known to be good for the health of human beings can be deleterious to the health of an individual who insists on consuming inordinate amounts of it, the committee agrees with the Food and Drug Administration that, instead of insisting on proof beyond any possible doubt that no harm will result under any conceivable circumstances from the use of a particular additive--which could, of course, occur if an individual decided to eat a pound of salt or drink 4 gallons of pure water in an hour--the test which should determine whether or not a particular additive may be used in a specific percentage of relationship to the volume of the product to which it might be added should be that of reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal, subject to the procedural safeguards provided in the bill which assure the right to hearing and judicial review.²

This standard, embodied in what is often called the "general safety clause" of the Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act (FFDCA), has applied, since 1958, to all food additives. FDA regulations implementing this standard, require the demonstration to a reasonable certainty that the

¹ House Report No. 2284, 85th Congress, 2nd Session, Committee on Interstate and Foreign Commerce, July 28, 1958.

² Senate Report No. 2422, Committee on Labor and Public Welfare, 85th Congress, 2nd Session, August 18, 1958.

substance in question is not harmful under the intended conditions of use. These regulations, which specifically adopted the language contained in the legislative history,³ outlines the factors to be considered in making a safety determination. These factors include 1) **probable consumption** of the substance, 2) **cumulative effects** in the diet, taking into account chemically or pharmacologically related substances, and 3) **safety factors** which in the opinion of qualified scientific experts are "generally recognized as appropriate."⁴

An example of FDA's application of this standard can be found in FDA's decision to issue a food additive regulation permitting the use of the nutritive sweetener aspartame.⁵

In 1960, the same standard was adopted by Congress for color additives. Under section 706(b)(4) of the FFDCA, the so-called "general safety clause" for color additives, a color additive

³See Federal Register (FR) vol. 41, no. 177, pp. 38644-5, September 10, 1976, and FR vol. 42, no. 199, October 14, 1977.

⁴Title 21, Code of Federal Regulations (CFR) Section 170.3(i).

⁵Aspartame; Commissioner's Final Decision, FR vol. 46, no. 142, pp. 38283-308, July 24, 1981; Aspartame; Denial of Requests for Hearing; Final Rule, FR vol. 49, No. 36, pp. 6672-82, February 22, 1984.

cannot be listed for a particular use unless the data presented to FDA establish that the color is safe for that use. Although what is meant by "safe" is not explained in the general safety clause, the legislative history makes clear that this word is to have the same meaning for color additives as for food additives.⁶

FDA has incorporated this concept of safety into its color additive regulations. Under 21 CFR 70.3(i), a color additive is "safe" if "there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive." Therefore, the general safety clause prohibits approval of a color additive if doubts about the safety of the additive for a particular use are not resolved to an acceptable level in the minds of competent scientists.

An example of FDA's application of this standard can be found in the final rule to permanently list D&C Green No. 5 for use in drugs and cosmetics excluding use in the area of the eye, published in the June 4, 1982, Federal Register (FR).⁷ When

⁶ House Report No. 1761, "Color Additive Amendments of 1960," Committee on Interstate and Foreign Commerce, 86th Congress, 2nd Session, 11 (1960).

⁷ FR vol. 57, No. 104, pp. 24278-86.

this rule was challenged in court, the Sixth Circuit upheld FDA's interpretation that D & C Green No. 5 is "safe" under the general safety clause.⁸

⁸ Scott v. FDA, 728 F.2d 322 (6th Cir. 1984).

(The attachments held in the committee files follow:)

6

Attachments:

- A. House Report, No. 2284, 85th Congress, 2nd Session, July 28, 1958.
- B. Senate Report, No. 2422, 85th Congress, 2nd Session, August 18, 1958.
- C. Recodification of Food Additive regulations, Federal Register (FR) vol. 41, no. 177, pp. 38644-5, September 10, 1976, and FR vol. 42, pp. 14089-91, March 15, 1977.
- D. Title 21, Code of Federal Regulations (CFR) Sections 70.3(i) and 170.3(i).
- E. House Report No. 1761, "Color Additive Amendments of 1960," Committee on Interstate and Foreign Commerce, 86th Congress, 2nd Session, 11 (1960).
- F. D & C Green No. 5, Final rule, FR vol. 57, No. 104, pp. 24278-86.
- G. Aspartame, Commissioner's Final Decision, FR vol. 46, no. 142, pp. 38285-308, July 24, 1981.
- H. Aspartame, Denial of Requests for Hearing; Final Rule, FR vol. 49, no. 36, pp. 6672-82, February 22, 1984.
- I. Case law:
Scott v. FDA, 728 F.2d 322 (6th Cir. 1984).
- J. "History of Cosmetic Color Additive Regulation: Creative Maneuvering by FDA Bodes Well for the Future," Michael R. Taylor, Esq., Food Drug Cosmetic Law Journal (FDCLJ) 37, 152-162 (1982).
- K. "Food and Drug Administration Regulation of Color Additives--Overview of the Statutory Framework," Michael R. Taylor, Esq., FDCLJ 39, 273-280 (1984).
- L. "Evaluating the Safety of Carcinogens in Food--Current Practices and Emerging Developments," Joseph V. Rodricks, et al., FDCLJ 46, 513-552 (1991)

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Just a couple of comments.

First, as a California farmer, I would say that some of the recordkeeping provisions that we in California are under are also embodied in the administration's proposal and I really do believe that this is an area that the industry and farmers should accept because I believe it holds a promise of building a greater confidence to the public of what we are using.

I would like to address some of the concerns that were enunciated by my colleagues. I believe that the figure of 98 percent that the chairman was using is based on research published by Dr. Bruce Ames from the University of California at Berkeley, in which he contends there is a higher incidence of naturally occurring carcinogens that could no more meet the standards of Delaney than synthetic products.

I guess on the reasonable certainty of no harm, I was encouraged by what was implied in some of your comments that you are realizing that a zero risk standard is no longer acceptable, and also when you take that into the maximum-tolerated dose protocols and regimes, which appear to have been utilized in the past under Delaney on a straight line extrapolation from that maximum-tolerated dose, you are implying that you are going to start evaluating the toxicity and the potential carcinogenic potential of a material based on a threshold and more along a yield response curve versus a straight line extrapolation?

Dr. GOLDMAN. What we are proposing is that we look at the scientific data for the individual chemical and make the determination based on the best scientific determination we can make. That could involve using different procedures than some of the procedures we use today. It would certainly be different than what we do under Delaney where it is simply inducing cancer in animals requirement.

It could also involve, as we depart from guidelines in other ways if we have data that indicate there is something about the mechanism that is not relevant to humans or pharmacokinetics or other issues that we need to take into account. Threshold is just one of those issues; the threshold, no threshold issue.

That is what we are looking for. The ability to use the best science, make the judgment, get peer review from our science advisory panel, and be able to change that over the years as the science gets better.

Mr. DOOLEY. Another issue that I am concerned about, and Mr. Volkmer touched on it, is the restrictions on the export of products. Again from a California perspective where we have put in a regime in the registration process that some people contend is even more onerous than what is required at the EPA level, which has led to some not being registered in California for use, but are available in other parts of the country. Thus in many cases our farmers argue in California that we are at an unfair competitive advantage.

Are we not running the same risk if we are going to be providing for a registration process and a reregistration process that has an arbitrary sunset of every 15 years. Companies are going to have to make a financial calculation of whether or not it makes sense for them to reregister this product for use in the United States?

If we look at where registrations have been canceled voluntarily by the registrant and that decision was not made on the grounds of science, but on the grounds of economics that then could preclude that company from being able to export that product, which does in fact become a jobs issue in the United States.

I have a hard time accepting that as sound policy.

Dr. GOLDMAN. We don't find and we have looked at this, that of the 600 actives registered in the United States, that a vast majority of them have registrations in other countries that have similar registration programs to our own, and very few companies will put the time and expense into developing a new active ingredient and then not take advantage of that work and effort to get a registration in the United States to get registrations in other countries as well, and we don't actually see that there will be very much disruption at all in the commerce for our companies.

We do see some nice benefits for the companies. And one of the things we have seen is similar provisions under our drug laws where we cannot export a drug from this country that is not licensed in the United States or didn't influence a similar system in another country, and Mr. Taylor knows a lot more about that than I do.

One of the things that we have seen is that it gives our products a fantastic reputation worldwide. People feel that those products meet a very high safety standard. They are highly desired on the international market.

Mr. DOOLEY. I think that this is a section that really is going to have to undergo some significant revisions in order for a number of us to be comfortable with it. But it is almost a form of arrogance that we would contend that other countries cannot make a determination that can protect the safety of their citizens, that if we do not necessarily agree with their testing protocols, that we are not going to allow a product to be manufactured in this country.

I have another question regarding an area on which I have some concerns and I think Mr. Gunderson enunciated some of the concerns about the cost of the registration process and the limited amount of money that the EPA has to register some of these products.

In terms of priorities, on page 25, when we are giving the Administrator the authority to provide \$4 million annually to provide countries technical assistance in the safe handling of pesticides. It is pretty hard, I think, for myself and a number of my colleagues to justify spending \$4 million in this sector, when it is clear that we are facing an unfunded situation in EPA that allows for the re-registration and the registration of some of these materials which will provide economic benefit to our producers here.

Dr. GOLDMAN. There are a couple of benefits. AID already carries out programs like this. And a couple of the reasons are, one, this reduces the risk that there are going to be undesirable residues on imports; and two, it increases the credibility of the entire pesticide market worldwide when we provide this kind of technical assistance.

There is a sense that it is our responsibility, along with our privilege, that we make money off of these exports. It is our responsibility to export along with the technologies, the appropriate and safe

methods of using the technologies, which then actually encourages further adoption and use of the technologies.

It is advantageous for us as well as being the best thing for public health and the environment in other parts of the world.

Mr. DOOLEY. And I would not disagree with the rationale behind your comments, and if we were in an ideal world where we had unlimited resources, we would be able to do a lot of things, but in an environment where we are having to make tough fiscal choices, it is hard for me to justify an expenditure of \$4 million.

We have heard your comments on the inability of EPA to live up to the mandate on the reregistration of products.

Mr. STENHOLM. Mr. Allard.

Mr. ALLARD. Thank you, Mr. Chairman.

During the previous questioning, we talked about provisions in the administration's bill on FIFRA and how they applied to cases using cancer, for example, and I would like to continue with a couple of questions along that line.

The new cancer standard in H.R. 4396, on page 7, line 14 to page 8, line 4, it applies to both pesticides found to induce cancer when ingested by humans or animals, or determined on the basis of reliable scientific evidence to pose a potential dietary risk of cancer to humans.

My question is why do we have both of those clauses? Wouldn't the last clause, if we are concerned about scientific approach, be enough?

Dr. GOLDMAN. They are both there in order to make sure that we have the full range of ability to exercise scientific judgment about the induces cancer determination. And the first one is really a business of if there is testing or studies in humans. We don't test these things in humans but we might do epidemiological studies that indicates that the chemicals may induce cancer. But the second allows us to bring in other reliable scientific evidence and we think that it is very important that we be allowed to do that.

Mr. ALLARD. Can you give me an example of a chemical that would be caught in the first portion that would not be covered in the second portion?

Dr. GOLDMAN. Yes, I could actually. A good example is a pesticide that is called Alliette which causes bladder tumors in rats and one of my toxicologists has looked at this extensively and even though it meets the first clause D, causes cancers when ingested by humans or animals, when you look at the rats, it only occurs at the high dose level in testing and only when bladder stones have been formed as the result of the dosing.

You find in that same species of rats that when you get bladder stones, you get cancer for those rats and you also find that humans don't, one, get bladder cancer at the levels where you would expect to find residue levels on food; and two, humans don't get cancer from bladder stones.

That is the kind of case where if you have part A only or a Delaney-type situation, you would have to say "Yes, this induces cancers in animals," but if you look at the rest of the reliable scientific evidence, you might change your mind about that. So we think we need to be able to do that.

Mr. ALLARD. So with those two provisions, you are not trying to apply them in the most restrictive manner. You are trying to give the flexibility so that you may apply them in something other than the most restrictive manner.

Dr. GOLDMAN. That is true, but it could go the other way. When you review a body of scientific evidence, sometimes the determination goes the other way.

Mr. ALLARD. Do you have an example?

Dr. GOLDMAN. TES is a good example where initially in animal testing you didn't see the cancer problems that we ended up seeing with actual human exposures to the drug. I think it is important that we are able to use all of the scientific information making these determinations instead of having an induces cancer in animals type of determination.

Mr. ALLARD. There is another example that comes to mind. We are talking about excessive doses of particular chemicals in male rats and it resulted in kidney tumors, and then apparently these kidney tumors are just peculiar to the rats and they don't occur in humans and are you forcing a standard in animals that you are going to end up applying to humans when there would not be any common sense in trying to apply that to humans?

This is a concern that I have when we get into this area.

Dr. GOLDMAN. This is exactly the issue. It is similar to the Alliette issue, where if you look at the animal test data alone, you might make one set of conclusions, but in this case, if you look at the pharmacology, there is some suggestion that there is something unique in this group of rats that does not apply to humans.

This is the kind of data that we believe we should be able to evaluate and include in an evaluation.

Mr. ALLARD. I wonder if we could do something in the way that we phrase that takes care of some of those concerns so that we make sure that the most scientific basis approach, we don't lose so much discretion which would allow you to get away from that scientific basis.

Dr. GOLDMAN. That is what we are trying to do with this language. The policy aim here is to allow us to use all of the available evidence.

As I said, it can go the other way. We might have negative animal studies and then have the epidemiologists come in and say, but it is causing cervical cancer and you want to be able to take that into account and not only look in a narrow way at one set of tests.

Mr. ALLARD. I would like to make a couple of other points just in closing. I would have to agree with my colleagues on the committee who have expressed some concern about the 60-day suit deadline that you have here in the bill, the lesser of those standards that you responded to in a letter in less than 60 days.

I have to think of one member of this committee who asked your agency to respond to a question in 60 days and it took you 89 days. In light of that, certainly it is difficult to respond to one member of this committee in 60 days and yet you have a deadline of citizens suits of 60 days.

So I think you might want to keep that in mind whenever you are talking about those citizens suits.

Other point I would like to make in closing is that you gave, I think it was to Ms. Lambert, the fact that what was proposed here as far as rules and regulations you felt would add 5 cents to the cost of bread.

Dr. GOLDMAN. No, the cost of pesticides that you can attribute to the price of bread is a nickel. We would not be adding a nickel. We are talking about a \$5 billion industry. We would be adding a tiny amount.

Mr. ALLARD. But take it in relation to the cost of wheat in that bread. The cost of wheat in that bread is only 4 or 5 cents, so it is a big—when you think of it in those terms, it does have a big impact at the farmer's level where we are talking about the raw product going into the cost of bread, so it is—just keep that perspective.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. Thank you, Mr. Chairman.

Dr. Goldman, during our earlier discussions on the exports—and I can't say exactly what you said—you hopefully will remember it better, but it passed me at the time, and that is that there have been companies that have produced a product that would not be able to be registered in this country that has been exported to other countries for use? Is that correct; or words to that effect?

Dr. GOLDMAN. That is the concern. That is the concern that we want to prevent.

Mr. VOLKMER. I would like for you to furnish me in writing within a week—not 69 or 89 or 90 days—within a week, the name of every company that has produced such a product, the active ingredient that was included in that product, the use of that product for which it was to be used, to what country it was sent, and when this occurred.

Dr. GOLDMAN. I would love to promise you anything Mr. Volkmer, the problem is that if somebody hasn't asked us for a registration, I don't have information about the active ingredients. I don't know about the toxicity.

Further, there are no requirements under the law that I would have records from them about their exports or sales. There is absolutely no way.

I can provide you—the GAO did a report on this issue, and we can provide you with information from that. We have some information under section 17 that we can provide you with, but I don't want you to feel that I have promised to you that I can give you an exhaustive list here when under the law, most of that information we would not be required to have today.

Mr. VOLKMER. You give me what you have. I want to see this because you made a statement here. I want you to back it up.

[The information follows:]

The Administration's legislative proposal on pesticide exports has several components which would generally restrict the shipment of unregistered pesticides. In order to gain a representative understanding of the pesticides that will be affected by the proposal, EPA evaluated each element of the legislation and compared it with pesticide exports which were known to have occurred, based on required reporting by pesticide exporters from 1992. [NOTE: This information is also being provided to Representative Volkmer by letter.]

Under FIFRA Section 17(a)(2), exporters of unregistered pesticides must submit a notice to EPA in connection with the export of unregistered pesticides. Using information compiled from these export notices, EPA then matched this information with the applicable element of the proposal to develop a representative list of the pesticides whose export would be prohibited or restricted.

The following analysis matches each element of the export proposal against information on known exports of unregistered pesticides from 1992.

Prohibition on export of pesticides banned because of health risks.

The proposal would prohibit export of those pesticides which have been banned for all or virtually all uses in the U.S. based on health concerns. List 1 contains the pesticide active ingredients that EPA believes fall under this category. This list contains 50 pesticide active ingredients. The recent cancellation of mevinphos will likely lead to its addition to this list. From the information available to EPA on pesticide exports from 1992, two pesticide active ingredients contained in this list of 50 were exported that year (List 2).

List 1

Description: Pesticides nominated by the U.S. to the international Prior Informed Consent (PIC) program's Banned and Severely Restricted list due to concerns over a pesticide's effects on human health.

Total Number Active Ingredients: 50

Active Ingredient

1. aldrin
2. arsenic trioxide
3. benzene hexachloride [BHC] (vol. cancellation)
4. 2,3,4,5-Bis(2-butylene)tetrahydro-2-furaldehyde [Repellent-11]
5. bromoxynil butyrate (vol. cancellation)
6. cadmium compounds (vol. cancellation)
7. calcium arsenate (vol. cancellation)
8. captafol (vol. cancellation)
9. carbon tetrachloride
10. chloranil (vol. cancellation)
11. chlordane
12. chlordimeform (vol. cancellation)
13. chlorinated camphene [Toxaphene] (vol. cancellation)
14. chlorobenzilate (vol. cancellation)
15. chloromethoxypropylmercuric acetate [CPMA]
16. copper arsenate (vol. cancellation)
17. cyhexatin (vol. cancellation)
18. daminozide (vol. cancellation)
19. DBCP
20. decachlorooctahydro-1,3,4-metheno-2H-cyclobuta(cd) pentalen-2-one [chlordecone]
21. DDT
22. dieldrin
23. dinoseb and salts
24. Di(phenylmercury)dodecenylsuccinate [PMDS] (vol. cancellation)
25. EDB
26. endrin (vol. cancellation)
27. EPN (vol. cancellation)
28. ethyl hexyleneglycol [6-12] (vol. cancellation)
29. heptachlor
30. hexachlorobenzene [HCB] (vol. cancellation)
31. lead arsenate (vol. cancellation)
32. leptophos (Never received initial registration)
33. mercurous chloride
34. mercuric chloride
35. mirex (vol. cancellation)
36. nitrofen (TOK) (vol. cancellation)
37. OMPA (octamethylpyrophosphoramide)
38. phenylmercuric oleate [PMO] (vol. cancellation)
39. phenylmercury acetate [PMA]
40. potassium 2,4,5-trichlorophenate [2,4,5-TCP]
41. pyriminil [Vacor] (vol. cancellation)
42. safrole (vol. cancellation)
43. silvex
44. sodium arsenate
45. sodium arsenite
46. TDE (vol. cancellation)
47. Terpene polychlorinates [Strobane] (vol. cancellation)
48. thallium sulfate
49. 2,4,5-Trichlorophenoxyacetic acid [2,4,5-T]
50. vinyl chloride

List 2

Description: Pesticides from List 1 for which EPA received reports of export in 1992.

Total Number Active Ingredients: 2
Total Number Products: 3

<u>Active Ingredients</u>	<u>Product Name</u>
1. Ethylene Dibromide	EDB 100 (3 times)
2. Ethylene Dibromide	Soilbrom 30
3. Chlordane	Technical Chlordane Val

Conditional prohibition on export of pesticides banned in the U.S. because of environmental risks.

The second element of the proposal is a conditional prohibition on the export of pesticides whose use has been banned in the U.S. because they pose environmental risks, such as hazards to non-target species. Export of such pesticides would be allowed only if officials within the country of import made an affirmative request to the U.S. government to allow shipment of a specific pesticide. EPA currently considers that three pesticide active ingredients would be covered by this provision (List 3). In 1992, EPA received information that two of these three pesticides were exported (List 4).

List 3

Description: Pesticides nominated by the U.S. to the international Prior Informed Consent (PIC) program's Banned and Severely Restricted list due to concerns over a pesticide's effects on the environment.

Active Ingredient

1. monocrotophos (vol. cancellation)
2. carbofuran (vol. cancellation)
3. tributyltin compounds

List 4

Description: Pesticides from List 3 for which EPA received reports of export in 1992.

Total Number Active Ingredients: 2
Total Number Products: 2

Active IngredientsProduct Name

1. Carbofuran
2. Tributyltin

Furadan 95 MUP
Tintox 1045

Restrictions on export of "unregistered" pesticides.

The proposal also addresses "unregistered" pesticides. This category includes pesticides that EPA has never evaluated for registration or tolerance purposes, pesticides for which applications are currently under review, and pesticides which were once registered but are now canceled because of economic considerations, rather than risk concerns. There were 15 pesticide active ingredients and 65 formulated products exported in 1992 which appear to fall into the category of "unregistered" pesticides (List 5).

Export of this group of pesticides would be prohibited under the proposal unless the pesticide active ingredient has a tolerance or an exemption from the requirement for a tolerance under the FFDCA, or (1) the pesticide has been approved in at least three countries which perform comprehensive, independent scientific reviews of health and environmental risks prior to permitting a pesticide to be marketed; (2) the importing country participates in the international system of "prior informed consent" for pesticides in international trade or has equivalent provisions in place; and (3) for food use pesticides, the manufacturer has submitted an analytical method capable of detecting residues of the pesticide on imported food.

Description: Exported pesticides from 1992 whose active ingredient is not contained in a U.S. registered pesticide and is not cleared for use on food with a tolerance or tolerance exemption under the Federal Food, Drug and Cosmetic Act (FFDCA).

Total number active ingredients: 16
Total number of products: 66

<u>Active Ingredient</u>	<u>Product Name</u>
1. Alphacypermethrin	Dominex Technical, Alphamethrin, Bestox 5EC, Bestox 10, Bestox 10EC, Bestox Technical, Dominex(2), Dominex Tablets
2. Beta Farnesene	Trans Beta-Farnesene
3. Carbosulfan	Marshal 25 WP, Marshal 35 ST, Marshal 25% ULV. Marshal 25 EC(2), Marshal 4 EC, Marshal 25 TS, Marshal 250 ULV, Marshal 35 STD, Marshal, Marshal 480 EC, Marshal 5G(2), Marshal 40 DB(2), Carbosulfan 25 WP, Marshal 20 EC(2), Marshal 25 St, Marshal(R) 5G, Carbosulfan 5% G, Carbosulfan 25 EC, Marshal (R) Technical, Carbosulfan, Marshal/R/25ST, Marshal Technical 20%, Marshal Technical, Marshal 25 CE
4. Difethialone	Difethialone
5. Exo-1-methyl-4-(1-methylethyl-2)(2-methylphenyl-2)	Cinch
6. Fluroxypyr	Fluroxypyr Methyl Ester
7. Flusilazole (aka Nuarimol)	Nustar 20 DF, Punch, Nuarimol, Nuarimol Technical
8. Furan	CN-1291, Great Lakes EF40/10, EF40/10, EF40/10P, EF-40
9. Haloxyfop	Haloxyfop R, Gallant 125 EE Herbicide, Haloxyfop ME-F (2), DE 535, Gallant, Haloxyfop, Gallant EEF
10. Haloxyfop-methyl	DE 535
11. Machete	Machete Herbicide
12. Prothiophos	Tokuthion(2)
13. Silane	H6573 Isomer Salt
14. Simetryn	Simetryn Technical
15. Thiazopryr	Thiazopryr, Thiazopryr Herbicide

Requirement of analytical method.

The proposal further requires that there be an analytical method capable of detecting pesticide residues on food for all exported pesticides. An exemption to the export prohibition would be created for pesticides which are to be used in a manner that is unlikely to result in residues in imported food, as in the case, for example, of many disinfectants and pesticides intended for rodent control. It appears that 25 pesticide active ingredients and 43 pesticide products exported in 1992 may fall into this category, unless it can be shown that they are unlikely to result in residues. (List 6. NOTE: This list includes some pesticides for which food uses are registered in the U.S., even though they do not have tolerances.)

The requirement for an analytical method would also apply to registered pesticides, if they have no U.S. food uses but might be used on food crops overseas and result in residues in imported foods. Therefore, the number of potentially affected pesticides may actually be larger than that reflected in List 6.

List 6

Description: Exported pesticides from 1992 whose active ingredient is contained in a U.S. registered pesticide but for which there is no tolerance or tolerance exemption under the Federal Food, Drug and Cosmetic Act (FFDCA).

Total number active ingredients: 25

Total number of products: 43

<u>Active Ingredient</u>	<u>Product Name</u>
1. 1,3-Dichloropropene	Telone II, Telone C-17
2. 2-(3,5,6-Trichloro)	Triclopyr Ethyl Ester
3. Acifluorfen	RH 6201 HP, Acifluorfen
4. Ancimidol	Ancimidol, A-Rest
5. Bayluscide	Bayuscide 70% WP
6. Bromadiolone	Super Card Blocks
7. Carbendazim	Airmilled Carbendazim, Carbendazim Technical, Delsene 50 DF
8. Dienochlor	Pentac WP
9. Diphacinone	Clean Crop Diphacin Meal, Clean Crop Diphacin Block, Clean Crop Diphacin Liquid, Diphacin 120
10. E-4-Tridecen-1-YL-Acetate	E-4-Tridecen-1-YL-Acetate
11. E-8-Dodecen	E-8-Dodecen
12. E-8-Dodecen-1-YL Acetate	E-8-Dodecen-1-YL Acetate
13. Flurprimidol	Cutlass, Flurprimidol
14. Isopropalin	Isopropalin EC, Paarlan E.C.
15. Isoxaben	Gallery Dry Flowable, Snapshot
16. Methylisothiazolinone	Experimental Biocide XB 1, Kathon LX Plus
17. Rozol	Dia-Rat Rozol, Rozol
18. Sodium Tetrathiocarbonate	Enzone, Enzone 612-EUP -1
19. Sulfosate	Banish
20. Sulfuryl Fluoride	Vikane Gas Fumigant, Vikane
21. Terbutylazine	Terbutylazine, Micromix Herbicide
22. Tricosene	Z-9 Tricosene (2)
23. Z-8-Dodecn-1-OL	Z-8-Dodecn-1-OL
24. Zinc 2 Pyridinethial	Omacide P-DOP-20
25. Zinc Omadine	Zinc Omadine Powder (2)

Note: The number 2 in parenthesis indicates a second appearance of the same product.

Enforcement of Prior Informed Consent.

The proposal also contains a provision which would allow governments to specify pesticides that should not be exported to their country. This provision would be triggered by notification to EPA from the importing government. It could apply to both registered and unregistered pesticides. If governments invoke this provision, they must certify that they are not manufacturing the pesticide for use within their own country or importing the pesticide from another source. It is not possible to estimate the number of pesticides that could be affected by this provision.

Research and development pesticides.

Finally, the export proposals contain an exemption from export restrictions for research and development pesticides. The purpose of the exemption is to ensure that businesses doing research and development work on new products in the U.S. are not disadvantaged by the strengthened export controls. Once a new product has reached the test marketing stage, however, the provisions pertaining to unregistered pesticides would apply.

Dr. GOLDMAN. We feel it is important—that it is important to trust this——

Mr. VOLKMER. I don't care what you feel. I want fact. I think the public should have facts, not what you think may be going on or what you suppose may be going on.

Dr. GOLDMAN. We can get you information that pertains to your question in 2 weeks. No promises that it is a comprehensive and complete list.

Mr. VOLKMER. I want to know.

Now, another question I have—and I have been sitting here listening to all of this talk about the sunset and the reregistration. Now, as I understand it, we are going to sunset all of these products that have been approved by EPA at one time or the other. Correct?

Dr. GOLDMAN. That is correct.

Mr. VOLKMER. The active ingredients, the formulation, nothing has changed?

Dr. GOLDMAN. That is correct.

Mr. VOLKMER. What has changed to make them suspect so that they have to be reregistered?

Dr. GOLDMAN. They would not be suspect and it would not be a drop dead, but the science does change. Our testing protocols change, and that is why we want a periodic review to simply update.

I would not want to start over from scratch, but simply update the data that we have in the agency on the pesticide.

Mr. VOLKMER. All right. Would you furnish me in writing the requirements that will be necessary after the sunset to reregister?

Dr. GOLDMAN. We certainly can.

[The information follows:]

Generally, the Administration's registration renewal, or "sunset," proposals mandate that pesticide registrations be reviewed on an active ingredient basis on a 15 year cycle, dating from the time of initial registration or a reregistration eligibility decision (RED) issued under the amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) enacted in 1988. The purpose of this provision is to ensure that the data supporting pesticide registrations are kept up-to-date with current scientific standards on a regular basis.

In order to maintain their registrations, pesticide registrants would be required to submit a complete application by year 12 of the review cycle. The data requirements that would be required to be met would be those in effect 4 years prior to the reapplication date. EPA is required to publish guidelines that clearly set forth each study that must be submitted, so that registrants will know what is needed well in advance and can complete the necessary studies.

There would be no requirement to repeat studies already submitted to EPA as part of the initial registration or RED; rather, the goal is to keep updating the data base to reflect changes in the data requirement guidelines made since the initial registration decision or RED. For example, as EPA moves to implement the recommendations of the 1993 National Academy of Sciences report on Pesticides in the Diets of Infants and Children, it is likely that additional testing requirements will be imposed. The implementation of registration renewal, or "sunset" provisions will promote consistency and help ensure that older pesticides meet the same safety standards required of newer pesticide products undergoing initial registration.

Mr. VOLKMER. Because I envision that what you are doing is going to cost the general public some more money for no purpose whatsoever. Because you have a provision in the law, and I believe it is continued under this, that if you do suspect that there is or if there is evidence that there is a product or an active ingredient that is carcinogenic or is toxic, that you can require the data on it to disaffirm or deny that, correct?

Dr. GOLDMAN. What the sunset provision would do is make our data call-in process a more orderly process of updating periodically every single pesticide's registration.

Mr. VOLKMER. All you are doing is going through a process of trying to—you got out here—how many would you suspect after re-registration that would still be OK to be used?

Dr. GOLDMAN. It is hard to predict over any given period, 15 years in the future, what the changes will be. But what we are talking about is what our changes have been under part 158, in the interim between when the pesticide got its last registration and when the sunset date is.

Again, it is not a drop dead date, it is not a provision that requires an entirely new risk benefit determination. This is simply a way to provide some order to the process of keeping registrations up to date so that we are no longer faced with what we had with reregistration with so many of them that were 30 to 40 years out of date, which then became an enormous logistical problem to deal with. We are simply trying to make this a more routine process, like the issuance of any other kind of license.

Mr. VOLKMER. Do we have products that have been registered and approved for 30 or 40 years in this country?

Dr. GOLDMAN. Yes, we do. The first time that we had pesticide registrations was in, I think, in 1951—1947. So under our reregistration program in the law being passed in 1988, we had some that were literally 30 or 40 years out of date in terms of the data base.

Mr. VOLKMER. And how many of those have been denied registration?

Dr. GOLDMAN. How many REDS have we denied?

Mr. VOLKMER. Can you send it to me? No, no, those that have been registered before, and came up for reregistration, how many have been denied? I would like to have that in writing.

Dr. GOLDMAN. We can get that to you in writing.

[The information follows:]

Since enactment of the accelerated reregistration program mandated by Congress in 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA '88), the number of pesticide products subject to reregistration has dropped from 45,000 to about 20,000; while the number of active ingredient "cases" has fallen from approximately 600 to 405. These changes primarily reflected discontinuance of lower use pesticides whose production and/or sales did not warrant continued registration in light of the fees and new data requirements imposed under FIFRA '88. (EPA has no way to ascertain definitively which pesticides may have been dropped because of risk concerns, rather than economic reasons, but a number of these products were no longer in production.)

More importantly, the generation of new, more up-to-date scientific studies as a result of reregistration data requirements has enabled EPA and registrants to take steps to reduce pesticide risks that may not have been systematically identified in the absence of the FIFRA '88 reregistration program. EPA's policy is to address newly discovered risks immediately, often long before the scheduled FIFRA '88 reregistration eligibility decision. If the risk appears serious enough to warrant cancellation, or a determination that pesticide uses are not eligible for reregistration, EPA takes action as soon as possible.

EPA has taken interim risk reduction measures affecting many pesticides. Such measures include label changes to better protect the environment and improve worker safety as well as lowered tolerance levels for residues in food. Many or all uses of a number of pesticides have been removed from the market based on new evidence of risks identified as part of the reregistration program and in conjunction with incident reports. All uses have been cancelled for 12 chemicals; some uses were cancelled for 16 additional chemicals. Use restrictions have been imposed on 26 chemicals.

To cite a few notable examples:

- o Over 80 uses of the pesticide ethyl parathion were voluntarily removed from the market due to worker risks.
- o Carcinogenic risks posed by EBDC pesticide uses in food were reduced by the elimination of a number of the uses of these fungicides.
- o As result of avian toxicity concerns, a number of actions have been taken to reduce risks posed by 14 granular pesticides, including lower application rates, use cancellations, and other measures. Ninety-five percent of granular carbofuran uses are being eliminated.
- o Most recently, all uses of the pesticide mevinphos were being cancelled by the manufacturer in light of EPA's concerns about acute worker risks.

Mr. VOLKMER. My last question. Do you know of any studies that have applied—following along the question of the chairman—that has determined that there may be suspect of any naturally grown fruits or vegetables that may be carcinogenic?

Dr. GOLDMAN. There is a study underway right now by the National Academy of Sciences that the EPA is helping to support, that is looking at this question of naturally occurring carcinogens in foods, that we are expecting a report from in the next 2 years, on what a consensus of a scientist might be. There have been a couple of individuals who feel very strongly that this is an issue, but what we are looking for here is some kind of a sense of the concurrence of the scientific opinion on this issue. And I believe that this expert committee that the National Academy of Sciences has assembled will provide us with a lot of guidance in this area.

Mr. VOLKMER. You are saying there has been no study of any fruits and vegetables before as to carcinogenicity of any fruits and vegetables?

Dr. GOLDMAN. The only good data on carcinogenicity are for aflatoxins. The other data that people often refer to are on tests that are done in petri dishes on bacteria looking at mutagenicity. That is the ability to change the genetics of the bacteria. And although we know that there is some correspondence between mutagenicity and cancer, we also know that it is not an absolute correspondence.

And I certainly don't consider that to be a determination of carcinogenicity. Otherwise we would have all kinds of things that we call carcinogens that just don't do that when you give them to animals. And so I am hopeful, though, that this study will help us get a better handle on the question.

Mr. VOLKMER. Mr. Chairman, if I may have just about another 30, 40 minutes, because all of this discussion—

Mr. STENHOLM. I object.

Mr. VOLKMER. Thirty seconds then, 30 or 40 seconds. All right. Because all this discussion goes back, Mr. Taylor, to something that occurred in this Congress back in 1978, as a result of the predecessor to our present chairman of the FDA, by the name of Dr. Kennedy, with a proposal to ban a substance called saccharin.

And in the discussions that occurred up here and in the Congress at the time, if Congress hadn't acted, saccharin would no longer—would not have been available in this country for the period since that time. Agreed? Agreed.

Mr. TAYLOR. That is correct.

Mr. VOLKMER. That is correct. Now, we have gone 16 years with the use of saccharin in this country. How much cancer have we got as a result of the use of saccharin?

Mr. TAYLOR. I don't have a quantitative answer to that question. There have been epidemiological studies that—I don't know how conclusive they have been. We can try to pull something together for the record if you would like that.

Mr. VOLKMER. I would like to have that, and because what I envision is going to occur unless this Congress does otherwise, we continue to use saccharin, if Dr. Kennedy was right, then we are going to have cancer all over this country in a few years. Surely 20 years, that is, only 4 years away, 20 years of constant use of

a cancer-causing substance like saccharin would surely cause somebody to have cancer, especially my wife. She is using it all the time. [The information follows:]

"How much cancer have we got as a result of the use of saccharin?"

Extensive human epidemiological studies have been conducted on artificial sweeteners. In particular, in 1985, the National Academy of Sciences (NAS) conducted a review of the carcinogenic events related to the use of cyclamates. The latter review incorporated epidemiological data on all artificial sweeteners including saccharin. In 1993, the World Health Organization (WHO) also reviewed epidemiology studies on saccharin. Both reviews indicated that within the limits of sensitivity of epidemiology studies, there is no increase in cancer as a result of the use of saccharin.

Relevant excerpts of the following reports are attached for the record:

Evaluation of Cyclamate for Carcinogenicity, Committee on the Evaluation of Cyclamate for Carcinogenicity, Commission on Life Sciences, National Research Council, 1985.

WHO Food Additives Series: 32. "Toxicological evaluation of certain food additives and contaminants," prepared by the 41st meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 1993

(Attachments are held in the committee files.)

Dr. GOLDMAN. Well, not to scare you, but there is some epidemiological evidence out of Canada that indicates that there may be an increase in cancers from saccharin, but it is not definitive evidence. And once you have a product that is in the market where so many people consume it and it is very difficult to assess what our exposures to it really are, doing that kind of study is just fraught with difficulties.

But as I said, there is some evidence, albeit not very strong, that there is actually a small increase, a very small increase, in cancer from saccharin.

Mr. VOLKMER. From saccharin?

Dr. GOLDMAN. That is correct.

Mr. VOLKMER. That was a Canadian study?

Dr. GOLDMAN. A Canadian study.

Mr. VOLKMER. Guess what, the original study was Canadian, too, if you remember. It all came from Canada. Does Canada permit saccharin? No. Do they?

Dr. GOLDMAN. I think they use——

Mr. VOLKMER. The study was from Canada, the original study was from Canada.

Mr. TAYLOR. I think saccharin is not approved in Canada, but cyclamate, a sweetener not approved here, is——

Mr. VOLKMER. Pardon?

Mr. TAYLOR. My understanding is that saccharin is not approved in Canada.

Mr. VOLKMER. That is what I understand.

Mr. TAYLOR. There are other artificial sweeteners that are.

Mr. VOLKMER. Yes. Well, that was just a sidelight. But you know, I have to look at everything in perspective as we go through life. And I heard all the time about all these things that were going to cause cancer all the time, and nobody ever looked at some of the things that I understand.

I may be wrong because I am not an epidemiologist at all, I am not even a biologist, but I have heard all these things are going to cause cancer all these years, and people keep living and don't die of it, and I just don't understand it. I really don't.

Dr. GOLDMAN. I think that we don't want people running around concerned about low level cancer risks. On the other hand, one in four of us does die of cancer. One in three of us gets cancer. I mean that is kind of an incontrovertible fact. I think we all know people who have cancer, have had cancer, have died from cancer, and we are all concerned about cancer.

The problem here has been that we, I think, haven't grappled with this in a rational way, that we either tend to ignore the problem or we go overboard. And what we are really trying to look at here is just a rational approach to dealing with the problem, a reasonable science-based approach.

Mr. VOLKMER. I couldn't agree with you more, but I think we should look at the full picture and not just part of the picture. You agree with that?

Dr. GOLDMAN. Absolutely.

Mr. VOLKMER. All right. Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Farr.

Mr. FARR. Thank you, Mr. Chairman.

Harold, I am more worried about your smoking than your wife's saccharin. You know, it is interesting as we sit here eating California raisins, thinking about how California through initiative process enacted the toughest food safety laws in the country on pesticide use, herbicide use in the State, and it has been very difficult for our farmers to have to live by those very tough, stringent rules. Yet they have, and we are still the No. 1 ag producing State in the Nation.

And it is interesting because what it has also had with it is a benefit that people know that the food coming out of that environment is safe, and it has had a marketing aspect to it that is, I think, also beneficial for the whole American food chain, and that is as we sell our products abroad, we can command higher prices for those products because they know that there is quality in them and they know that they are safe. And so there is a benefit to all this.

But right now, as we try to debate how we are going to rewrite the law and we all agree that the Delaney clause needs reform, think as the debate heats up, that we are not talking really with weakening food safety law, more about updating the law to current technology. And as we do that, I just—a couple things occurred in the discussion that I heard this morning.

One that I would like to know is how many registered pesticides, including those on minor crop pesticides, are we or have tolerances that are set by the EPA using the de minimis principle? Do you know what the answer to that might be?

Dr. GOLDMAN. I think we have something like, correct me if I am wrong, 6,000 tolerances—9,000 tolerances that we set. And we believe that all of those tolerances, whether we are talking about a tolerance that we have set for an individual agricultural use, some of them are for uses in transit and in storage as well. All of those need to meet a health-based standard.

Currently today, something like a quarter of those, if you look at them very carefully, they are somewhat above what we would consider to be a health-based standard. Now, when you look even more carefully, you see that the actual levels on a dinner plate are lower. And part of what we are trying to get at here is we are trying to get away from this disparity between what we can enforce and what we want to provide as a standard. We want to toughen the standard so that it reflects a health-based standard.

Mr. FARR. Well, in light of that, in the administration's suggested policy on benefits consideration which would disallow the consideration of benefits in setting the tolerances 10 years after enactment, I believe that you are going to have to have some kind of reasonable criteria for the benefits part of the equation. I believe that you also have to define the bottom line safety standard beyond which health risks are unacceptable, no matter what the benefits are.

Your answer to Ms. Lambert's question was essentially one that it seemed to me you are going to have a bifurcated process, you are going to have one at the farmgate, another one at the supermarket level or dinner plate level. But why does not the administration want to move policy toward—or why are you not allowing some benefits standards to be considered in your policy? Or are you real-

ly setting those benefit standards at different levels, a level at the farmgate and another level at the dinner plate?

Dr. GOLDMAN. I think it is really two separate issues. I think the issue of permitting a dual system allows us to have an enforceable health-based system that also takes into account what is needed for good agricultural practice. And you might call it a benefits consideration because that is a benefit for the farmers, but we are also looking at that as something that fits a kind of a reasonableness criterion for having an enforcement system that is reasonable.

On the other hand, in terms of the issue of what the standards should look like, we believe that the standard for levels of pesticides on food does need to be a safety standard and that we can and should provide consumers with the assurance that the food that they eat is safe. That is only fair. And we think that we can do that without significant disruptions in the long run, as long as we have the ability to do a reasonable transition.

Mr. FARR. Well, as one member of this committee, I would like to help you implement that, and also I would like to be on record that I am one that strongly believes in a fee-for-service, and I think that your fee schedule is reasonable and appropriate.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Kingston.

Mr. KINGSTON. Thank you, Mr. Chairman.

Dr. Goldman, this is a kind of a big picture question, not specific on this, but would you say that it is true that EPA or other Government agencies bend their studies to reflect political policy? Or would you say that EPA and other Government agencies are always true to empirical science and not the waves of political agendas?

Dr. GOLDMAN. I think generally that Government science, Government scientists, have integrity and generally that they expect for themselves that they adhere to the same principles of good science, peer review, as scientists anywhere. They are also just about as competitive with each other as scientists anywhere.

I also think that you can find examples not only within the Government but also within universities and various places where people have bent science to meet other aims, whether it is a policy direction or to show a finding that they don't find. And that it is important for the Government, like the university systems and everybody else, to have very stringent standards of peer review and appropriate mechanisms for dealing with fraud or misconduct if that does occur. I think it is very rare, both within and outside the Government, that that does occur.

Mr. KINGSTON. Would you say that scientists have a lot of peer pressure on their peers as a group to come up with the same studies? For example, if a scientist came up with something that was contrary to what had been the consensus, would he or she be under some unwritten peer pressure to squelch the results of their study?

Dr. GOLDMAN. No more in the Government than anywhere else. I think that generally in the scientific community that there is a tendency for scientists to get hung up on paradigms and it is hard to shake them loose from those once they get stuck on those. I don't think that is true more in the Government than anywhere else, though.

I think that, generally, if you come up with something that is fundamentally different and new, that you had a greater case to make than when you come up with something that fits within the generally accepted paradigms of science. I think that is true everywhere, though.

Mr. KINGSTON. So if there is somebody, say in the EPA, who came out with a study, that says there is no problem with a secondhand smoke and, under this administration, obviously there is a problem with secondhand smoke—and I am only using that for an example, I know we are Delaney clause here—but that scientist would not be kind of pushed to the back of the room and say that ain't what we are looking for from this particular study at this time?

Dr. GOLDMAN. I believe that that scientist's work would receive appropriate peer review as well as supervision from the people who supervise the person. And if the work were deemed to be of high quality and to meet the tests of peer review, and in science that is a highly rigorous and competitive process, then I believe that that information would be incorporated in the agency's assessment of secondhand smoke.

What often happens and creates controversy is that of course sometimes when people come out with findings that are at odds with the current paradigms, it is because they didn't do the work very well. And under those circumstances, then I think that the peer review needs to also say we don't incorporate that into our assessment, because it doesn't meet our standard.

Mr. KINGSTON. Now, on the situation with fraud that you had mentioned, and I am just kind of jumping back around here with the Alar scare on apples several years ago which cost thousands, I presume millions of dollars to certain people in the industry, was that an EPA study or who—who came up with that?

Dr. GOLDMAN. I can describe that and actually we have an apple grower on the panel here who might want to add to this, who went through that episode. No, it was not. It was a—what happened is we had a study from the registrant that had been contracted out and it had been performed at an earlier time, and an earlier point in time before some of the good laboratory practices that we now use had been placed into practice.

So it met the standard at the time it was performed, it really was not fraudulent or a bad study, but the standard changed. And because the standard changed, when the scientists reviewed the study, they said, yes, this is a study that appears on its face to be a positive study, but it doesn't meet our modern-day standard in each and every way for a toxicity test for cancer, and therefore we would recommend that it be repeated.

And then there was the issue of under that circumstance what does the agency do about it, and that is where the decision was made, really we couldn't take action, and I think you know the rest of the story where eventually the apple growers voluntarily took action on their own because of the concern that that created.

And, Larry Elworth, I don't know if you want to add to that.

Mr. ELWORTH. Not as far as the toxicology.

Mr. KINGSTON. Let me ask you this: In terms of your power to do something should a crisis like that occur again, do you have the

power now and is that something that if you don't have the power, that should be incorporated in a bill so that EPA could show the leadership to save jobs, help the industry out and so forth?

And I am assuming in this case there was overreaction. There are other cases where there might not be overreaction. But should you have something to give you the responsibility and the option to do something?

Dr. GOLDMAN. Yes, and you know the administrative conference of the United States also agrees with us that basically what we need, and this is right out of their report in the Federal Register, is a phase down procedure that allows us, when we have those kinds of questions about risk and benefit, to take an action to begin to phase down the use, while the extra data, the other information, are being generated so that we are not ever again in a position where the EPA tells the public we are helpless in the face of this risk concern and we can't do anything which is, in my opinion, and it is just an opinion, what created much of the scare around the Alar situation.

Mr. KINGSTON. Thank you, Dr. Goldman. Mr. Chairman.

Mr. STENHOLM. Any other questions from anyone?

Mr. Smith.

Mr. SMITH of Oregon. Thank you.

Dr. Goldman, back to the sunset issue for just a moment. And by the way, this is a drop dead—well——

Dr. GOLDMAN. It is not a drop dead.

Mr. SMITH of Oregon. Well, look on page 7, if you want to, section F, extension. It is 15 years in your bill, and for an additional 1 year, that is drop dead. On page 7, there is no other amending language, it is a drop dead program, 15 years, 1-year extension.

Now, the question I have is simply this: Again, with the thousands of applications you have, you are way behind, you will depend upon future funding by the Congress if you are going to catch up by the year 2004. Would you consider language that would somehow provide that if a registrant participated in good faith and that the fault of the reregistration or the registration was for some delay in the EPA or they couldn't get to it, that you could give them extended opportunity?

They acted in good faith, why can't we make a test? Rather than apply the bureaucratic problem to it, why can't we change it around to a good-faith effort by the applicant?

Dr. GOLDMAN. Well, that is what we believe this provision does, and we are certainly willing to work with you if you feel it doesn't meet that. We certainly don't want a registration to expire and it is not the intent of this for registration to expire simply because we didn't open the mail.

Mr. SMITH of Oregon. They lose their priority position, they go to the bottom of the list, that is crazy. I mean, that doesn't make any sense to anybody. Beyond that, you have the deadline suit problem in your bill, if it is your fault, then you are going to be sued by the applicant or the registrant, you are going to be in court trying to tell them we didn't have enough funding from Congress, we couldn't get to you. I mean, we need to correct that, I think.

Dr. GOLDMAN. I think that it is also something we can work with you on, where it came from in that case was the sense that, boy,

if we are going to commit ourselves to a schedule, that we, the agency, for the sake of credibility of that commitment, need to be willing to submit ourselves to that kind of—

Mr. SMITH of Oregon. That is fine. I think you stepped over the line. We will work with you. Thank you.

Mr. STENHOLM. Does the administration support a statutory provision providing for national uniformity of pesticide tolerance?

Dr. GOLDMAN. That is an issue that we were not able to get to in developing our bill. We understand that that is a major concern of many members of the committee and this is something that we would like to work with you on.

Mr. STENHOLM. Thank you very much. We appreciate your attendance here this morning. We look forward to working with you expeditiously over the next several days and weeks, getting a bill.

Our colleague Rich Lehman is here, and we will recognize you at this moment for your input into the subcommittee hearing before we call the second panel.

I recognize our colleague, Mr. Lehman. Welcome.

STATEMENT OF HON. RICHARD H. LEHMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. LEHMAN. Thank you, Mr. Chairman. I want to commend you once again, as I did last August, on taking the lead in addressing the very serious question of food safety. This hearing and the one last summer on the Lehman-Bliley-Rowland bill are significant steps toward a full understanding of the issue, and I believe the best avenue for reform.

It is difficult not to be both encouraged and disheartened at the same time at the Clinton administration's recent introduction of food safety reform legislation. I am encouraged that the three leading agencies—EPA, FDA, and USDA—have finally agreed upon a package that can be closely reviewed here in the Congress. I am disappointed, however, that upon review, it seems their legislation fails to impose scientifically balanced risk assessments and real world scenarios in evaluating pesticide residues.

In a recent TV report, the question was asked, "Are we scaring ourselves to death? Have we created an environment where the real risks to public health are overshadowed by media attention devoted to sensationalist headlines? Is it easier to lead people to believe that any detectable pesticide residue, no matter how infinitesimal, is more of a threat than naturally incurring *Salmonella*, when the truth is, current residue levels are so stringent that they do not pose a risk to public health?"

Unfortunately, the administration in its proposal overcompensates for the perceived fears generated by such news stories instead of allowing accurate risk-based science to take its course. While the Clinton administration proposal projects to establish a negligible risk standard for both raw and processed foods, in essence, it sets a standard for restrictions that any vestige of flexibility is eliminated. In addition, the proposal eliminates benefits consideration, but allows for a 5-year waiver if the food supply is disrupted or consumer health is threatened.

On the one hand, the administration draws the conclusion that the only benefits derived from pesticide use are economic ones to

the grower, and then it turns around and acknowledges that the safe and limited use of pesticides provide for a healthy, abundant and affordable food supply.

The bottom line is that benefits accrue to everyone and give consumers something they have come to expect, fruits and vegetables free from scarring, pest infestations, and decay. I disagree with the administration's approach in other areas as well, including their phaseout provision, the lack of uniformity, exaggerated exposure assumptions, and multiple tolerances for a single pesticide. I do agree with the administration, however, in their special consideration for infants and children.

As I have stated repeatedly since the National Academy of Sciences' study was released, a children's standard must be incorporated into any legislation which is to pass Congress, including my proposal, H.R. 1627. In addition to the support of my colleagues, Congressmen Bliley and Rowland, H.R. 1627, the Food Quality Protection Act, has been cosponsored by a majority of the Congress.

While the administration has good intentions in bringing forward their own proposal, the fact remains that the approach put forward in our legislation reflects what is right about our current system, and what is needed to improve it. Flexibility does not mean weak standards nor does accurate risk assessment mean a lack of protection for public health.

Congressmen Bliley, Rowland, and I have asked Chairman Waxman of the Energy and Commerce Subcommittee on Health and the Environment to mark up our legislation, and I am here today asking the administration to work with us as well to see a workable food safety reform package passed in Congress. It is time to move beyond the rhetoric and ahead to serious discussions.

I welcome the opportunity to comment on the issue before you today, Mr. Chairman, and I look forward to working with the administration and others to make real progress on this very important issue in the coming months.

Thank you.

[The prepared statement of Mr. Lehman appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you very much, Mr. Lehman. We appreciate very much your leadership on this issue. The bill that you and Congressmen Rowland and Bliley have put together is certainly a tremendous effort in the right direction. You showed the leadership. We continue to appreciate that, on this subcommittee.

We wish you success working on the Energy and Commerce Subcommittee on Health and the Environment, to expedite the consideration of this legislation. In fact, if there is anything we can do to help you on that endeavor, we will try to do so. I will state to you, though, we intend to mark up and have legislation from this committee that encompasses the jurisdiction of the other committee as well as this committee, and we were encouraged by some of the responses of the administration along the lines of working to get a package together.

They were very forthcoming as far as I was concerned with that desire, and we intend to take them up on it, to see that we can in fact put together a proposal.

Mr. Volkmer, have you any questions of Mr. Lehman?

Mr. VOLKMER. No. Congratulations, that is all.

Mr. STENHOLM. We thank you for your leadership, look forward to working with you.

Mr. LEHMAN. Thank you, likewise.

Mr. STENHOLM. I call the second panel: Ms. Doyle, Mr. Maslyn, Mr. Stenzel, Mr. Schlect, Mr. Panetta, and Mr. Boillot. The first witness will be Ms. Becky Doyle, director, Illinois Department of Agriculture, on behalf of the National Association of State Departments of Agriculture.

We would ask each of our witnesses who testify to keep your oral remarks within the 5-minute rule, and ask you to summarize. Either during your testimony or in the questioning period be prepared to comment on what you have heard from the administration witnesses, and specifically on the bill that they have proposed as to your views, particularly between H.R. 1627, that bill, and what direction we should take on this committee.

Ms. Doyle, proceed.

STATEMENT OF BECKY DOYLE, DIRECTOR, ILLINOIS DEPARTMENT OF AGRICULTURE, ON BEHALF OF THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE

Ms. DOYLE. Thank you, Mr. Chairman. I am Becky Doyle. I am director of the Illinois Department of Agriculture, and a member of the board of directors of the National Association of State Departments of Agriculture, NASDA.

As the chief State agricultural officials, NASDA's members are keenly aware of the importance of balancing agricultural production and natural resource protection. In most cases, under a cooperative agreement with the Environmental Protection Agency, the State departments of agriculture serve as the lead State pesticide regulatory agency. As Dr. Goldman referred to us, we are their partners in pesticide regulation. So we bring you a unique perspective on pesticide regulations and reauthorization of FIFRA.

NASDA members represent the frontline pesticide regulators who must balance human health and environmental protection with production needs, and deal with State and local concerns about pesticide use and regulation. We feel American consumers can be confident that the U.S. food supply is safe from unreasonable risk presented by pesticide residues.

Domestic food products available to U.S. consumers are safe, abundant, and economical. NASDA does believe, however, that improvements in pesticide laws are needed primarily due to advances in scientific, technological capabilities. We believe that the bill just presented to you, H.R. 1627, will improve Federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a negligible risk standard, as recommended by the National Academy of Sciences.

Adoption of this legislation will allow the U.S. to continue to produce the safest, most economical, and most abundant food supply in the world. NASDA strongly supports passage of H.R. 1627 and encourages the House Agriculture Committee to move quickly to favorably report the bill as the vehicle used by this committee in reauthorizing FIFRA.

The previously discussed bills, H.R. 4329 and H.R. 4326, would implement the administration's plan with a focus on eliminating the use of pesticides rather than ensuring their safe use. Some of the proposals may sound sensible, but most are actually unworkably rigid and would create real problems for farmers and food producers. Most importantly, they are ultimately contrary to the best interests of consumers.

Adoption of these bills would lead to the loss of important safe crop protection tools for farmers, coupled with an increase in food prices and a decrease in availability and quality of food. For us, the most disturbing situation that has been created by H.R. 4329 and H.R. 4326 is the scenario that no pesticide regulation reform will be passed in this Congress.

We feel that the 103d Congress needs to pass reasonable pesticide regulation. Our members and the industry face problems created by conflicting and confusing regulations of FIFRA and the FFDCa, and consumers need to have their confidence in the food supply restored. Both of these objectives can best be achieved by passage of a bill, a bill which improves the situation; one which allows producers to enhance the quality and availability of a safe and nutritious food supply; H.R. 1627 accomplishes that.

Turning to specific issues, NASDA is especially concerned that a negligible risk standard not be defined by reference to a specific acceptable numerical risk level. It is essential that EPA maintain flexibility to take account of evolving scientific standards and to consider all relevant safety and exposure information.

H.R. 1627 would make clear that EPA may establish a tolerance for pesticide residue posing greater than a negligible risk if the agency determines that there are countervailing benefits. On the other hand, the administration proposal would greatly limit the types of benefits that could be considered in pesticide tolerance decisions, would prohibit the continuation of a tolerance based on exceptional benefits beyond 5 years, and would prohibit any consideration of benefits in tolerance decisions after 10 years.

NASDA strongly opposes this narrow benefits standard which would be virtually impossible to satisfy. We believe it is unnecessary to give EPA entirely new authority to phase out or phase down the use of pesticide where, "credible scientific evidence shows a pesticide is reasonably likely to pose a significant risk to humans or the environment."

NASDA strongly opposes the concept of citizen suits against EPA, State regulatory agencies, and commercial applicators for any violation of FIFRA as provided for in the administration's proposal. Such a provision is wholly unnecessary and only encourages frivolous lawsuits and disrupts State department programs and probably agricultural production. Also, NASDA strongly opposes expansion of the 1990 farm bill recordkeeping requirements to cover all farmers who apply any general use pesticides as provided for in the administration's proposal. As regulators of pesticide application and pesticide recordkeeping, NASDA's members believe such a provision would be absolutely impossible to enforce and equals an unfunded mandate.

In conclusion, Mr. Chairman, let me express our appreciation for the dedicated efforts made by this committee in attempting to pass

legislation addressing the issue of pesticide regulation. NASDA believes that H.R. 1627 is the best vehicle and will improve Federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a negligible risk standard, as recommended by the National Academy of Sciences. Adoption of this legislation will allow U.S. farmers to continue to produce the safest, most economical, and most abundant food supply in the world.

Thank you.

[The prepared statement of Ms. Doyle appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Mr. Maslyn.

STATEMENT OF MARK A. MASLYN, DIRECTOR, GOVERNMENTAL RELATIONS, AMERICAN FARM BUREAU FEDERATION, ACCOMPANIED BY SCOTT RAWLINS, HORTICULTURAL SPECIALIST

Mr. MASLYN. Good morning, Mr. Chairman. My name is Mark Maslyn, and with me is Mr. Scott Rawlins, our horticultural specialist for the American Farm Bureau. We appreciate the chance to be here and to present our views relative to the administration's bill as well as related matters. I commend you for holding the hearing, look forward to working with you to keep this issue moving forward in this Congress.

For the record, we support H.R. 1627. We believe that this is a good bill from which to build a reform of our Nation's food safety legislation.

Mr. Chairman, farmers and ranchers continue to be frustrated by the uncertainty that surrounds Federal pesticide policy in the United States. The uncertainty with the Delaney clause, the uncertainty with reregistration, the uncertainty over the loss of minor crop pesticides, the uncertainty over the arrival of new products and new technologies, and the uncertainty over this legislation.

We are looking for stability and predictability. We are looking for assurances that the tools that we need to protect our crop investments will be available. Simply put, that is our objective, not only available but safe to use.

In reviewing the administration's bill, we are disappointed that they did not strive harder to strike the necessary balance needed to resolve this long-standing issue. There was and perhaps still is an opportunity for them to assume that brokering role. We have privately and publicly urged them to do so.

We have a number of very serious concerns with H.R. 4362 and H.R. 4329, which we have elaborated on more fully in our written testimony. In general, however, the administration bill—the proposal seems to be excessive. It is rigid, it is bureaucratic, and it is punitive. I think it is reasonable to ask whether this proposal makes the system safer or simply more difficult to get through.

Too often, it seems to move away from, rather than toward, a common center. For the purposes of moving this issue forward, however, we have also tried to identify those areas where we agree conceptually and otherwise. Specifically, the issues of cancellation, integrated pest management, label call-in, reduced-risk pesticides,

moderate-use pesticides, are a few examples of where we believe there is an opportunity to work together.

The task of amending FIFRA and the Federal Food Drug, and Cosmetic Act should be done with clear purpose and intent of designing solutions to identified problems. The process simply is not able to sustain a wish list approach to amendments. Given the history of this issue, less is better.

With that premise in mind, there are several important areas that we think should constitute a core package of amendments. First, the primary objective should be to resolve the differences between FIFRA and the Food and Drug Act as they relate to pesticide registration and the tolerance setting process. Adherence to a zero risk policy is neither scientifically credible nor achievable. Coordinating those efforts through a negligible risk standard is essential to pesticide reform.

The immediate need to replace the Delaney clause is real. EPA has chosen to place that burden squarely on the Congress to avoid the potentially harsh effects of the application of the Delaney clause in the *Les v. Reilly* decision. In shifting the burden to the Congress, the agency has chosen to avoid other nonlegislative remedies that could avoid or soften the impact on farmers or consumers. In fact, they have taken every action to increase the potentially harsh impact on the farm community, in order to create pressure on the Congress to reform this law. We think this is unnecessary and irresponsible.

Second, legislation should create a single regulatory standard, applicable for both fresh and processed foods.

Third, there is a general consensus that the regulatory process for removing pesticides determined to present an unreasonable risk to health or the environment takes too long and it should be expedited.

Fourth, it is essential that newer and safer products and technologies be developed and approved for market more quickly to replace those being lost. The lack of replacement products is perhaps the most frequently voiced concern by farmers when discussing pesticide policy.

Fifth, the loss of pesticides for minor uses is particularly acute and needs to be resolved. Separate legislation sponsored by Chairman de la Garza and Senator Inouye would help address this concern. We believe the problem is time sensitive and needs to be addressed in this Congress. We are encouraged that the administration at least stepped up to this issue in some fashion.

Sixth and finally is the need to retain the risk benefit consideration in FIFRA and the Food and Drug Act. The benefits of pesticides accrue to all of society, not just to farmers. Consideration in the pesticide regulatory decisionmaking process is critical for a reasoned and coordinated policy.

I find it ironic that if you look at all of the major environmental statutes up before this Congress, there is a debate in every one of them about the need to consider benefits and costs along with a better risk assessment. And the Congress seems to be moving in that direction in each of those cases, except in this one, where the administration seems to be moving away from a provision in law that has worked basically for three decades.

We are concerned that they have not justified that position. I really don't understand why they are moving in that direction. What is the problem that we are trying to solve? The benefits of pesticide use must be balanced with risks along with the need to feed a world population that is growing by nearly 100 million people every year.

Mr. Chairman, we appreciate the opportunity and look forward to working with you.

[The prepared statement of Mr. Maslyn appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Mr. Stenzel.

**STATEMENT OF THOMAS STENZEL, PRESIDENT, UNITED
FRESH FRUIT AND VEGETABLE ASSOCIATION**

Mr. STENZEL. Thank you, Mr. Chairman, for the opportunity to appear before you on the panel today to testify on an issue of great importance to the fresh fruit and vegetable industry. My name is Tom Stenzel. I am president of the United Fresh Fruit and Vegetable Association. We represent 2,000 companies and their employees who grow, ship, distribute and sell fresh produce in the United States and abroad.

Mr. Chairman, we salute your leadership in this effort, for it is also our very strong desire to pass legislation in this Congress that provides for comprehensive reform of the Nation's pesticide laws. We know time is short, but the fruit and vegetable industry is ready to sit down with all interested parties and pursue real discussions on pesticide legislation.

We support an improved cancellation process to more quickly deal with problem pesticides, real Delaney reform to establish a negligible risk standard based in sound science and not prescription, consideration of consumer risks and benefits in tolerance setting, a commitment to provide regulatory incentives to registration of safe minor use pesticides, and a process that provides for speedier approval of a new generation of pesticides such as biologicals.

Many of the members of this panel share these concerns and will address these issues in more detail. We do believe that these and other issues can be addressed in a bill this year. Many of us in the agricultural community have awaited with great anticipation the administration's legislation. But despite the support of 222 Members in the House for H.R. 1627 and its companion bill in the Senate, it is well understood that neither bill is likely to escape the jurisdictional trap that contains them.

For this reason, we sincerely hoped the administration would craft a bill that would break the logjam that characterizes this issue. Unfortunately, they failed. The administration's bill has done very little to further the prospects for passage of pesticide legislation. To be fair, the administration's bill does address many important issues and attempts to bring form to numerous regulatory concepts that deserve discussion. But in some sense, this is its weakness.

The myriad of issues and concepts raised by the bill are very ill-served in passing legislation. The bill is simply too cumbersome, forces together too many different issues, and contains too many flaws to serve as the overall basis for compromise. Just listen to

what we talked about this morning: Citizen suits, sunset provision, export restrictions, FDA enforcement authority, a two-tiered tolerance system, whether it is farmgate or at retail. None of those elements are essential to the reform of our food safety laws and pesticide reform.

It seems we know what they were doing for that 8 months. They were putting everything on the table. Unfortunately, the broad scope of those reforms are overwhelming and they distract attention from the most important issues: cancellation provisions, incentives for minor use pesticides, a negligible risk standard in lieu of the Delaney clause, consideration of risk and benefits in tolerance setting, and national uniformity of pesticide tolerances.

I was struck with Mr. Inslee's comment this morning—maybe it is not risk-benefit that we are talking about in tolerance setting, it is considering all types of risks. We talk about cancer and Dr. Goldman mentioned that one out of four of us will develop cancer in our lifetimes. Health authorities are clear that the majority of cancer is directly attributed to poor nutrition.

The National Academy of Sciences report, which has been frequently cited this morning, has said that the benefits—the anticancer benefits of eating fruits and vegetables—far outweigh the pesticide risk. So why is EPA afraid to consider the consumer health benefits of an abundant, affordable fruit and vegetable supply—the anticancer benefits—as they take into consideration the tolerance process?

Before closing, Mr. Chairman, I would like to commend you and ranking minority member Mr. Smith for the letter that was sent to EPA regarding its intentions to implement the Federal Court ruling in *Les v. Reilly*. As my colleague from the Farm Bureau has mentioned, the EPA has refused to consider administrative options that would certainly lessen the impact of the implementation of that court ruling. The agency was petitioned some 21 months ago, on September 11, 1992, by our organization, the National Food Processors, the Northwest Horticultural Council and other groups, with the support to EPA to revise its Delaney clause policies.

This petition has yet to be answered by EPA, although we at each stage have new lists of potential problem chemicals and tolerances that may be revoked, for seemingly the express purpose of creating anxiety, causing disruption in the marketplace, and pressuring the Congress to take on a burden that EPA could bear administratively.

The agency must identify when and how it will implement the Delaney clause because this continued delay simply raises anxiety and disruption to our farmers. Administrator Browner has stated plainly that the issues surrounding the enforcement of *Les v. Reilly* turn on legal interpretations and not on public health. But despite this fact, EPA has not acted to resolve the unnecessary conflict between its pesticide policies and the Delaney clause.

We hope, Mr. Chairman, that the committee might urge more decisive leadership by EPA on this issue as an important administrative step the agency could take to facilitate serious discussion of pesticide reform legislation.

Thank you.

[The prepared statement of Mr. Stenzel appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Next, Mr. Schlect.

STATEMENT OF CHRISTIAN SCHLECT, CHAIRMAN, MINOR CROP FARMER ALLIANCE, AND PRESIDENT, NORTHWEST HORTICULTURAL COUNCIL, ACCOMPANIED BY DANIEL A. BOTTS, CHAIRMAN, TECHNICAL COMMITTEE, MINOR CROP FARMER ALLIANCE, AND DIRECTOR, ENVIRONMENTAL AND PEST MANAGEMENT DIVISION OF THE FLORIDA FRUIT & VEGETABLE ASSOCIATION

Mr. SCHLECT. Thank you, Mr. Chairman. My name is Chris Schlect. I am chairman of the Minor Crop Farm Alliance, which comprises 134 local, regional, and national commodity organizations interested in solutions to the minor-use issue. We were formed about 3 years ago for the specific purpose of working on the minor-use issues and, therefore, will contain our comments to that portion of the administration's bill. You have plenty of other experts discussing the other sections of that measure. Dan Botts, who is with me and will be discussing a few points in a few seconds or minutes, is from Orlando, Florida, is the chairman of our technical committee.

I think it is important to note our organization is commodity based, producer oriented, and goes beyond the food safety issues. We have Christmas trees, we have flowers, we have livestock, fruits and vegetables. It is a wide ranging commodity organization built around getting a solution to the specific issue. We have worked hard the last 3 years coming up with suggestions, worked with this committee staff and members, Chairman de la Garza has entered a bill that is sponsored by many members of this subcommittee addressing the minor crop issue that we believe will aid us in this problem and we would hope that that legislation or the initiatives in the administration's proposal will be adopted this year.

It is necessary that it is done because of the harm that our producers are facing because of the lack of support for minor crop chemicals. I think one of the points we would like to put forward is the encouragement that we do have on this one issue based on the administration's acknowledgment of the problem, the Congress' acknowledgment.

Everybody, I think, can see what we are faced with when we have chemicals that are necessary for production, yet the manufacturer doesn't want to spend say, \$1 million or even \$100,000 to go through a process when that chemical may only net \$70,000 or \$50,000 in sales. Minor crops is somewhat of a misnomer. I think of apples being a major crop. Dan thinks of citrus being a major crop. And yet in the vernacular in Washington, DC., they are minor crops.

I think it is important that we get a solution that the definition of minor crops truly covers the problem that we are facing in the minor crop area, which is almost all areas of agriculture outside the five major crops. But with that, I just want to convey the sense

of urgency. We have given testimony, written testimony to the committee on the specifics.

We intend to work with the committee and with the Senate, the administration. We want a bill. We want a solution to this process. If not in the context of the administration's proposal, then perhaps a stand-alone measure that again Chairman de la Garza is sponsoring. But now turn it over to Dan for specific comments.

[The prepared statement of Mr. Schlect appears at the conclusion of the hearing.]

Mr. BORTS. Mr. Chairman, I am pleased to be here again today to go over again an issue that is very near and dear to my heart. And attached to our written testimony is a comparison of the provisions of the administration's minor-use provisions along with what we have put together and you, in conjunction with Chairman de la Garza, so graciously sponsored as H.R. 967, the minor crop amendments that were put in earlier this session.

In a direct comparison, there is some specific things that we would like to address, the first being in the definition of minor uses which is found in section 10 on page 74 of the administration's proposal. The legislation would establish criteria by which a pesticide use is automatically considered a minor use, in essence establishing a bright line.

There are problems with the criteria in that it needs to be revised to include those nontraditional use sites which are also minor uses such as livestock uses and public health uses which are non-economic from a registration standpoint. Additionally, the farmgate value or potential return to a crop is an unnecessary restriction, it should be dropped from the definition.

There was an addition into the definition of three criteria to the economic provisions. We would recommend that those three additional criteria be removed from the definition to constitute when it would be considered for expedited consideration or if they have to remain we would recommend adding a fourth recommendation that a pesticide that is necessary for an integrated pest management program to be successful, to be included.

Also in section 10, the adequate time provisions for submission of minor-use data, we would recommend that the first sentence of subparagraph (n)(1) should be revised to indicate that the Administrator on the request of a registrant or at the request of a user with the consent of the registrant may delay action to delete a minor food or feed use. This would provide a greater involvement of the user community and an earlier involvement in the decisionmaking process as those tools are possibly lost.

In addition to those very specific comments, consideration should be given to requesting Congress to modify the administration's bill to add a number of provisions contained in H.R. 967 which are not yet part of the administration's proposal. In particular, the proposed grant program and the establishment of minor-use programs within both EPA and USDA should be included.

And in conclusion, Mr. Chairman, we believe that the differences between H.R. 967 and the minor-use provisions of H.R. 4329 are minor and are quickly resolvable, and we believe this issue can and must be resolved this year. And we look forward to working with you and Chairman de la Garza to enact this minor use legislation.

Thank you.

Mr. STENHOLM. Next, Mr. Panetta.

STATEMENT OF JOSEPH PANETTA, DIRECTOR, REGULATORY AND ENVIRONMENTAL AFFAIRS, MYCOGEN CORP., ALSO ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

Mr. PANETTA. Thank you, Mr. Chairman, and thank you, the members of the subcommittee for inviting me to be here to testify today. I am going to confine my remarks to section 9 of the administration's proposal, the section concerning biological pesticides and reduced-risk pesticides. I am Joe Panetta, I am director of regulatory affairs for Mycogen Corporation in San Diego.

At Mycogen, we use biotechnology to increase food and fiber production by developing environmentally compatible biopesticides and improved pest resistant crops. I would like to note for the record also that I am here today testifying on behalf of the Biotechnology Industry Organization. BIO represents more than 500 companies, academic institutions, State biotechnology centers and other organizations involved in the research and development of health care, agricultural, and environmental biotechnology products.

Last September, the Clinton administration announced a pesticide reform program aimed at reducing chemical pesticide usage and promoting the development of reduced risk alternatives, including biopesticides. BIO member companies publicly commended the administration for taking action in promoting the use of biologicals, an action which we believe long overdue.

Mr. Chairman, both you and Chairman de la Garza have long shown foresight in this area and have taken interest in ensuring continued registration of minor-use pesticides, a category that includes many of the biologicals and reduced-risk pesticides that we are interested in. In a regulatory climate focused on reducing pesticide use and with public and media attention centered on the potential dangers of pesticides, it is important to ensure that farmers can address these concerns while continuing to produce wholesome and affordable food.

As you said at last year's hearings, all new methods of pest control that add to the farmers' diminishing arsenal, and that promise safe and effective results should be considered for use. BIO heartily endorses the EPA's intentions regarding biologicals and separately reduced-risk pesticides, as expressed in section 9 of the proposal to amend FIFRA.

In testimony given in your hearing on the registration process last year, biopesticides industry representatives stated that the regulatory process for biopesticides was simply not working and that EPA needed to implement management changes to speed up the registration process and to dedicate specific resources to the review of biologicals.

EPA has already moved forward to address these recommendations. We believe that the following steps which are the most significant to us of the many progressive changes proposed in section 9 will ensure that the industry has greater incentive to develop reduced risk and biological products and that they are made available to farmers more expeditiously.

First, criteria for the designation of reduced-risk pesticides will be developed by EPA. While EPA issued reduced-risk pesticide policies last year, it did not define the scope of products to be considered. And this would remove that uncertainty.

Second, specific timeframes for the review of reduced-risk pesticides. Review times for acceptance of a product for reduced-risk consideration would be mandated, and actual review of the product would be completed within 180 days. The trade-off for expedited review would be immediate revocation of the registration if at a later time the product were shown not to meet the reduced-risk criteria. We believe this is a fair trade-off.

Third, exclusive use of data extended by 2 years. This section ensures both that applicants of these products are provided additional incentive for protection of relatively low-cost data packages, as compared to traditional chemistry, and addresses some concerns about the removal of older minor-use products from the registration roles.

Fourth, conditional registration of biological pesticides. Past experience with biologicals has shown that, due to their unique nature, they do not typically raise human health or environmental concerns. This section would allow our industry to move these products into the hands of farmers quickly, while we develop the data needed for registration, provided that the EPA can conclude on the basis of available data that the use of the product is in the public interest and that the product does not raise risk concerns.

Fifth, integrated pest management. IPM practices are applicable to all of the products that we produce, but of even greater significance is the fact that many small producers of biological pesticides lack the field specialists needed to introduce farmers to these products. This provision would assist us in providing this knowledge to farmers.

We urge you to support the provisions of section 9 in your consideration of the administration's overall proposal for amendment of FIFRA. And I would also note that these provisions are not included in Mr. Lehman's bill.

In contrast to the last 16 years, these sections look to the future. They provide for the registration, and hence the availability to farmers, of a new generation of products that are already being produced by large and small companies alike. Much progress has been made by EPA in the last year since you last held hearings, for which the new management team is to be commended.

The administration's proposal brings to the registration process for reduced-risk pesticides a degree of definition and certainty that has previously been lacking. Thus clarified, this process will move forward.

In conclusion, Mr. Chairman, this bill proposes some simple changes to the registration process for biologicals and reduced-risk pesticides that will certainly bring more of these desirable products to the market. If Congress makes a commitment to expedited registration of these products, research and development will intensify and both old and new companies will provide farmers with much needed environmentally safer additions to their pest-control arsenal.

We commend you for your effort in this area. We look forward to working with you in the future.

Thank you.

[The prepared statement of Mr. Panetta appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Mr. Boillot.

**STATEMENT OF JAMES B. BOILLOT, EXECUTIVE DIRECTOR,
NATIONAL AGRICULTURAL AVIATION ASSOCIATION**

Mr. BOILLOT. Mr. Chairman, members of the committee, thanks for the opportunity to be here this morning. Thank you for the leadership that you are showing in this area.

I am Jim Boillot, executive director of the National Agricultural Aviation Association. Our association represents over 1,200 members and represents the agricultural aviation industry nationwide. Our review of the provisions contained in the proposal, in the administrative proposal, suggests this legislation could have far-reaching effects on agricultural aviation, Mr. Chairman, more importantly, on American agriculture and the consuming public.

The agricultural aviation industry is made up of approximately 6,000 special-use airplanes and helicopters which are used to provide seed, fertilizer, and agricultural chemicals to this Nation's fruit and vegetables, feed grains and fiber and forest producers. Simply stated, agricultural aviation enhances crop production, protects our forest resources, and controls health limiting pests and pathogens.

Mr. Chairman, we appreciate the interest which you and your colleagues are taking in this issue. As we study the provisions of this legislation, we are concerned with the suggestion of a new philosophy, that places no relevance on the benefits which can result from the use of pesticide products.

Tremendous benefits in the form of improved human health, efficiencies in food production, elimination of deadly pathogens, and the ability to farm without erosion-producing tillage, have resulted from the use of agricultural chemicals.

We are all concerned with the safe use and application of chemicals and sincerely want to avoid unnecessary risk to any segment of our population or the environment. Currently, EPA is able to weigh the real and demonstrable benefits of pesticide use against known or theoretical risk. We believe it is essential that this recognition of the benefits that can result from the proper use of agricultural chemicals must be maintained as a factor in the determination of approval or disapproval of specific products.

Another area of concern to ag aviators is the provision allowing citizen suits against those applying agricultural pesticides. There is substantial knowledge and training involved in developing the capability to correctly apply a chemical; and I might add, to determine if a product is being correctly applied.

From our experience, and I think we all know airplanes are highly visible, we know that there are people who become easily mistaken regarding what is happening in an application situation. The determination of compliance with correct usage and application requirements should remain as the sole purview of regulatory officials.

Mr. Chairman, this proposal contains language establishing as a goal the reduction in the amount of pesticides that are used in production agriculture. To our knowledge, there is no scientific data suggesting that a product requiring ounces per acre provides more safety than a product requiring pounds per acre.

We acknowledge that it may be politically expedient to state that pesticide usage has been reduced, but we suggest that it is far more appropriate to base registration and reregistration decisions on scientific data and to leave use decisions to those who have a clear understanding of the targeted pest and the conditions surrounding a specific application.

We believe a goal of reducing the amount of crop protection chemicals can be counterproductive and we urge the Congress to encourage a philosophical goal of safe, economical, high quality food production, and care to assure that generations that follow us have that same opportunity of providing safe, economical food for their enjoyment. We believe this is a realistic goal that can be accomplished when using the best scientific data to determine product approval and labeling instructions.

We are also concerned with the language throughout the proposal suggesting that registration fees should be utilized to cover all manner of increased review and regulatory cost. The greatest beneficiaries of food production technology improvements are the American consumer. And in the long run, we believe they would be willing to pay for increased cost for regulatory activity if it is necessary.

The American farmer is not in a position to pass these costs on and should not be asked to accept the burden of increased regulatory activity.

Mr. Chairman, we very much appreciate the desire of your subcommittee to determine what is best for all, the producer, the consumer, the environment, and future generations. We are grateful for the opportunity to comment and look forward to working with you to develop legislation that will guide the use of crop production chemicals and will assure the consumers of this Nation a safe, high quality food supply, produced without damage to the environment.

Thank you.

[The prepared statement of Mr. Boillot appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you very much. I commend each of you for your written statements that you furnished for the record. It gives us an excellent basis to work from. And I think I would be remiss if I did not say I believe this is the first panel that I have ever had the privilege of chairing, which you stayed within the 5-minute rule and did so in a concise way in which you made absolute good sense. So to reward you for that, I will not ask you a question.

Mr. Inslee.

Mr. INSLEE. I pass.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. No questions.

Mr. STENHOLM. Thank you all very much. We appreciate your interest in this subject and your testimony. We will ask you to roll up your sleeves and to work with our staffs and with Members to

do just exactly what you have asked us to do and, hopefully, as close to the way you have asked us to do it as humanly possible.

Thank you very much.

I call panel 3: Mr. Wiles, Ms. Hinkle, Mr. Feldman, Mr. Meyerhoff, and Mr. Schwartz.

Mr. Wiles, proceed.

STATEMENT OF RICHARD WILES, DIRECTOR, AGRICULTURAL POLLUTION PREVENTION, ENVIRONMENTAL WORKING GROUP

Mr. WILES. Thank you. Mr. Chairman, distinguished members of the subcommittee, thank you for the opportunity to testify today. We will focus our comments on administration proposals to amend the Federal Food, Drug, and Cosmetic Act.

The Environmental Working Group supports the general public health orientation of the administration's legislative proposals, particularly the proposal to end benefits consideration in tolerance setting. As a consensus position of the USDA, the FDA, and the EPA, this proposal to create a truly health-based tolerance system is particularly laudable.

In general, however, the Clinton proposals, while well-intentioned, fall short of the mark. This is particularly true in contrast to H.R. 4091, introduced by Congressmen Waxman, Synar, and Torres, which provides an affirmative scientifically sound alternative to the Delaney clause that increases public health protection and ensures protection of children from all pesticides.

I would like to make a few specific criticisms now of the administration bill. First, it sacrifices the Delaney clause rather than refining it. The administration proposes to remove pesticides from under the Delaney clause and to compensate for this loss with the discretionary health-based standard that is, in theory, designed to protect children. By effectively repealing the Delaney clause as it applies to pesticides, the administration would eviscerate the only preventive environmental health standard in all Federal law.

The spirit of prevention embodied in Delaney would be lost, and nothing remotely equivalent would be substituted. More than any other provision of the administration's package, this change is unacceptable. In contrast, the Waxman bill, H.R. 4091, would refine the concept of prevention that is the essence of the Delaney clause, and replace it with a stronger, more rational phaseout requirement.

Point two, the administration's safety standard for children is discretionary. Protection of children must be mandatory. Standards in the law must not provide the EPA with discretion to set weaker standards for infants and children based on economic benefits to farmers or any other consideration. At the same time, Federal law should not constrain science, nor prescribe specific risk assessment methods, and neither the Clinton nor the Waxman proposals do.

What the law should provide instead is a firm and certain standard of protection for all children, regardless of the political orientation of subsequent EPA Administrators or any other economic or political factors. The Waxman bill guarantees this protection. The Clinton bill does not.

The administration does not explicitly protect infants and children from carcinogens.

The National Academy of Sciences states that young children may be at increased risk from carcinogens where lifelong exposure is thought to be responsible for the effect, and where exposures that occur early in life are likely to be more significant in producing cancer.

To protect children from heavy exposure to carcinogens early in life, the Waxman bill requires that exposure to cancer-causing pesticides not be disproportionately accumulated in the first 5 years of life. The administration bill includes no specific cancer standard to protect infants and children.

For pesticides that do not cause cancer, the administration's bill does not provide children with additional safety margins.

Cancer is a very crude measure of toxicity. Many noncarcinogenic pesticides present hazards to children that are as serious or more serious than cancer, such as damage to the immune, nervous, and endocrine systems.

In the absence of data relevant to children, the National Academy of Sciences recommended that up to a tenfold safety factor be applied to all food tolerances. The administration's legislative proposals propose an additional tenfold safety factor, but then allow it to be compromised solely at the administrator's discretion. The Waxman bill, in contrast, requires a tenfold safety factor, allowing for it to be eased only when complete and reliable data support a lesser standard.

The administration bill does not protect children from the additive effects of pesticides. The NAS committee was clear that exposure to many different pesticides can cause additive effects and that children need extra protection from these combined effects. In fact, the NAS committee went so far as to devise a new methodology to determine exposures and set standards that protect children from the combined effects of pesticides. The administration bill, however, does not contain a requirement to protect children from the added effects of pesticides. The Waxman bill does.

The administration bill contains no specific data requirements with respect to children. Although the EPA has begun some internal processes to develop new study designs, there is no requirement in the administration's legislation that appropriate studies be developed or conducted. In contrast, H.R. 4091 requires the EPA to establish testing protocols and data to determine whether exposure to a pesticide during fetal development, infancy, or childhood, can cause serious adverse health effects.

In summary, the administration's proposed amendments to the Federal Food, Drug, and Cosmetic Act represent a reasonable starting point for discussion, with one important exception; the lack of any effective alternative to the Delaney clause. The Clinton proposal to simply eliminate all preventive aspects of current pesticide law is plainly unacceptable from a public health perspective.

While the Delaney clause can be made more consistent and scientifically rational, there is no improving on the core concept of Delaney, which is the prevention of exposure to the most hazardous pesticides in the food supply.

Thank you.

[The prepared statement of Mr. Wiles appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Ms. Hinkle.

**STATEMENT OF MAUREEN KUWANO HINKLE, DIRECTOR,
AGRICULTURAL PROGRAM, NATIONAL AUDUBON SOCIETY**

Ms. HINKLE. Mr. Chairman, I will be very brief so that you will reward me, but hopefully not by not asking questions. If you don't have questions for me, I would like to answer some of the questions posed to previous witnesses which I feel were not answered.

In general, we fully support and endorse the statement given today by Richard Wiles on behalf of the Environmental Working Group, and we commend the administration for its ambitious and unprecedented effort involving the three agencies in a working group, including the bureaucrats who work on the details of the respective jurisdictions in pesticides, as well as the new appointees.

It is unprecedented for such a team to put together a document seeking amendments to two major laws the way they have. However, we regard this as a first step, and not an end product.

I will reserve my comments today to section 9, which is the reduced-risk pesticides. It seems to be the only provision in the administration's bill that got much support from the previous witnesses. In regard to reduced use, we are unhappy that the criteria and definition of reduced use is not in the legislation. By leaving it to rulemaking, this will merely postpone regulation and incentives for reduced use pesticides by many more years.

I know that the agency hopes to use the three conferences that they have sponsored on reduced use to give the agency the necessary wherewithal to produce criteria, but if they think that they can use these three conferences in order to get the criteria developed, I think this is unrealistic.

The guidelines that they have had in place since 1981 for biological pesticides, that is subpart M, have not been implemented in all this time, even though the regulations were greeted by unanimous praise by all the companies that went to hear about them. These guidelines were developed by the American Institute for Biological Sciences for the agency. The agency didn't even have to develop them internally.

Three years ago, EPA Administrator Bill Reilly announced "imminent" policies regarding safer pesticides. The gestation period for biological pesticides is a record 17 years, and it will go on to 20 if the legislation doesn't specify what the criteria and what the definition should be.

Without a legislative mandate, EPA prefers to take no action rather than make a mistake. And although the agency has been moving rapidly in recent months to improve its record of registering naturally occurring products, this sudden haste could actually harm the development of new alternatives.

Naturally occurring products are not inherently safe or unsafe. Their toxicity and their nontarget effects need to be evaluated according to their use, their exposure and other characteristics in a deliberate and orderly procedure. The administration bill would provide registrants the opportunity to designate a product a re-

duced use pesticide. Then EPA would decide whether or not it is a reduced use pesticide. This is backwards.

A lot of registrants will try, hoping that somehow EPA will find them to be a reduced use pesticide. This is just not an orderly process. Similarly, conditional registration is to be given to reduced use pesticides. They can have a registration right away, if they seem to be less toxic, and then when they get all the studies in, they will have a full registration.

We think that this can apply to conventional chemicals or many of the new registrations of chemicals but not to the new generation of biologicals, which should get on the market really very quickly. They should have an easy on and an easy off process. Should there be problems that are detected after the registration, they should be quickly knocked off without recourse.

The administration's proposal mentions resistance a couple of times, but they really don't address it in an integrated way and we think that it is really necessary. They also would provide for use by prescription, but they have nothing about qualifications of the prescriber. They don't even mention the possibility of liability.

Conflict of interest, that is prescribing products that the prescriber has a financial interest in, is also not dealt with. And unless these issues are dealt with, we feel that prescription use will once again fall into the trash basket as it has in the previous 15 years.

With that, I will close.

[The prepared statement of Ms. Hinkle appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Mr. Feldman.

STATEMENT OF JAY FELDMAN, EXECUTIVE DIRECTOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. FELDMAN. Good morning, Mr. Chairman. Thank you for the opportunity to testify today. I am Jay Feldman, executive director of the National Coalition Against the Misuse of Pesticides. Today I am presenting this testimony on behalf of 25 international, national, statewide, and regional environmental, consumer, farm, and labor organizations that work on a day-to-day basis against the backdrop of poor Federal and State policies that allow pesticide contamination and poisoning, and offer limited incentives and assistance for the adoption of pest management strategies.

While the polarization that you have referred to in this hearing and previously is not new to this subcommittee, I think it is instructive to look at what has been accomplished in the past, particularly 1988, with the adoption of FIFRA light, which I would characterize as language that everyone could live with, language which met basic public health and environmental requirements at the time.

There was, in 1988, general recognition by the subcommittee that there was an urgent need to get the pesticide reregistration program moving ahead, that we had to eliminate certain basic impediments to regulatory action in the form of costly indemnification. The subcommittee also bit the bullet and established a fee-for-service reregistration program.

Now we are in—6 years later, 1994, and we expect to see in Congress increasing recognition of new urgent needs. And the two urgent needs that we see and we hope Congress will see is, first, to ensure the orderly removal from the market of pesticides that cause identified adverse human health or environmental effect, including but not limited to cancer, endocrine and reproductive effects, the highest category of acute effects, bioaccumulation and persistence; and second, that Congress will see the need to provide direction and support for economically and biologically viable pest management alternatives that do not rely on chemically dependent control strategies.

What is different today from 1988—and there are some important differences—first, we see increasing numbers of farmers that have shown an openness to options that move their operations away from dependence on pesticides. Second, environmental and health advocates—and public health advocates—are leading the charge on this whole issue are working with farmers and farm groups, and I believe exhibit a growing understanding of farmers' needs for productive and profitable farming operations.

Any proposal for pesticide policy change or reform must be measured against a set of principles that serve as the minimum national standard of public health and environmental protection. And I think you were very correct this morning to cite the GAO report in which, and I am quoting out of context here, "Because scientific data are not always adequate to quantify risks and benefits, the choice of an appropriate regulatory standard entails value judgments, and is ultimately a policy decision."

We believe it is an abuse of science to suggest that it is possible to draw a bright line standard of protection given the incomplete and inadequate data currently available on a range of critical issues, including again, but not limited to, sensitive population groups, multiple exposure to pesticides, and threshold chemical effects.

And it should be noted for the record, that improvements in detection technology since Delaney's adoption does not change the inability of science to establish the threshold at which effects like cancer occur. We support fully implementation of the preventive health policy principle now embodied in part in the Delaney clause of the Federal Food, Drug, and Cosmetic Act. We advocate legislative and regulatory actions to extend the Delaney principle to include prohibitions against residues in raw as well as processed foods.

In addition, we advocate for nonagricultural pesticides to be subject to the same regulatory provisions as agricultural pesticides. In written testimony, we outline a series of principles, the first being enforceable phaseout of toxic pesticides for defined effects, and measurable and enforceable as well as voluntary incentive-based reduction goals.

Point of purchase disclosure, full pesticide reporting, prohibition against export of pesticides that are banned, severely restricted or never registered, effective retraining and other assistance programs for displaced pesticide production workers, protection of State and local authority to regulate pesticides more stringently than the Federal Government.

There is a basic standard we are trying to measure these proposals against. We must evaluate proposals against the only meaningful yardstick, and that is will the measures ensure that we are removing hazardous materials from the market while affecting a transition to alternative approaches?

While we too would like to commend the Clinton administration for taking on this issue, we believe very strongly that the proposals fall short of the central and critical issue of public health protection and preventive health policy as related to a series of adverse health and environmental effects. We have cited cancer, endocrine system effects, et cetera.

We have looked at the Waxman bill in particular, many of the groups on this document supporting this testimony, as the only proposal for a Congress that embraces the prevention principle of the Delaney clause. In our testimony, we cite other areas of the Clinton bill in more detail that we think need improvement.

And I would like to say in closing that while our position stresses the need to look at a range of adverse effects, the importance of attacking cancer causing pesticides is critical in an environment where one in three people contract cancer during their lifetime. This is a national crisis and a true crisis in the farm population, where farmers suffer elevated rates of numerous types of cancers.

This year, the University of Iowa Medical School presented preliminary results to the Golf Course Superintendents Association of golf courses being a highly intensive pesticide treated area and there too found elevated rates of cancers among golf course superintendents, again, preliminary results.

We have an opportunity to join in a national effort to remove toxic pesticides from food production and pest control. Our future rests with clear protective human health and environmental protection standards and a clear commitment to an aggressive national program to assist in the transition to sustainable alternatives, not reliant on pesticides.

Thank you.

[The prepared statement of Mr. Feldman appears at the conclusion of the hearing.]

Mr. DOOLEY [assuming chair]. Thank you, Mr. Feldman.

At this time, we will hear from Mr. Joseph Schwartz who is associate director for Policy for Physicians for Social Responsibility.

Mr. Schwartz, please proceed.

STATEMENT OF JOSEPH M. SCHWARTZ, ASSOCIATE DIRECTOR, POLICY, PHYSICIANS FOR SOCIAL RESPONSIBILITY

Mr. SCHWARTZ. Thank you. On behalf of more than 20,000 PSR members in 90 chapters nationwide, an international network of 125,000 physicians in 76 countries, I would like to thank you for the opportunity to address some of the public health implications of the administration's pesticide reform proposal.

In the interest of time, I would like to focus on three basic things. I know you have heard a fair deal about the National Academy of Sciences' report. If you would bear with me, I would like to highlight a few elements of that report that I think are particularly relevant and have not been discussed in adequate detail.

The three basic items I would like to focus on are the National Academy report as a diagnosis, what the prescription of that report was, and the extent to which the administration pesticide proposal fills that prescription. The National Academy of Sciences' report was the most comprehensive diagnosis to date of the effects of modern chemical pesticides, particularly on the most vulnerable members of society.

The Chair of the NAS committee, Dr. Philip Landrigan, and committee member Dr. Richard Jackson, are both members of PSR's board of sponsors. The NAS report concluded several important things, not least of which was that children's pesticide exposure may be far greater than adults even within the same home. Children, especially newborns, absorb many pesticides more quickly and detoxify many pesticides more slowly than adults.

In addition, early exposure has been implicated in childhood and other cancers, noncarcinogenic effects on the developing nervous, immune, and endocrine systems. In particular, the central nervous system is unusually vulnerable during a prolonged period of development, even if exposure is at a level known to be safe for adults, one of the key discussions in the National Academy of Sciences' report.

As far as a prescription for pesticide policy reform, despite the research needs that the report detailed, the study concluded that we know enough to act now to prevent unnecessary childhood pesticide exposures. The study urged that regulatory estimates of safe levels of pesticide exposure aggregate all pesticide residues with a common toxic mechanism.

And most importantly, the National Academy of Sciences' study said that without, "contrary data, there should be a presumption of greater toxicity to infants and children." "Because of specific periods of vulnerability, an uncertainty factor of tenfold should be used in particular when data from toxicity testing are incomplete."

They concluded that, "traditional approaches to toxicological risk assessment may not adequately protect infants and children." The National Academy of Sciences' report offers an invaluable prescription from America's most eminent physicians and public health experts to reform pesticide policy. The question remains: To what extent has the administration's pesticide reform proposal followed the doctors' orders?

The overall goal of the Clinton administration proposal, reducing America's costly dependence on chemical pesticides, we feel is very commendable. Physicians will tell you that prevention of harm is by far the best basis for protecting public health. Some other worthy elements within the administration proposal are better data collection, expansions to raw food and safety testing from the farmgate through the retail level, strengthening enforcement to enhance action against the most toxic pesticides.

Potentially, the phaseout of known hazardous pesticides could promote investment, research and development and widespread farmer use of safer alternatives. Unfortunately, this provision is undermined by excess discretion in the administration proposal. On balance, we feel that the administration proposal is well intentioned but fails to fully implement some of the key recommendations of the National Academy of Sciences' report.

For example, given the current data gaps that the administration proposal hopes to remedy, the repeated requirement in the administration proposal that EPA shall account for available information in regulatory standard setting, would allow a lack of information to perpetuate a dangerous status quo with respect to childhood pesticide exposures, and could condemn the EPA to inaction.

The National Academy of Sciences' report clearly separated the need for additional information from the need to act now to reduce unnecessary pesticide exposures. Instead, a bill that some of the other members of this panel have discussed, H.R. 4091, the Waxman proposal, would apply a more protective presumption against continued exposure of infants and children to unnecessary pesticide residues.

Physicians for Social Responsibility would conclude that H.R. 4091 more accurately reflects the preventive public health prescriptions of the National Academy of Sciences' report, and represents a more effective reform of Federal pesticide policy than the administration proposal.

If I could just take a moment to focus on three specific areas that the administration proposal fails to fully implement the National Academy of Sciences' report, the first is in standard setting. We have heard something about the additional tenfold margin of safety that the administration proposal would allow.

Superficially, that is in keeping with the National Academy of Sciences' report. But the administration would only take into account the completeness of data as far as kids' exposure. The administration should require an additional margin of safety without irrefutable evidence that it is unnecessary.

In addition, as Mr. Wiles has already mentioned, the provisions with regard to multiple exposures and child specific testing, PSR thinks are handled much better in H.R. 4091 than the administration proposal.

In conclusion, I would say that pesticides are ubiquitous in Americans' diets and environment. Not all pesticides are equally toxic, neither are all pesticides equally necessary to farmers' prosperity. While researchers provide additional information that we need on the effects of pesticide exposures, prudent public health measures warrant protections against excessive exposure to pesticide residues, especially by infants, children and other vulnerable populations.

The administration proposal, while echoing some of the language within the NAS report, would not ensure that the National Academy of Sciences' representations would be fully implemented. We conclude that the administration proposal would not fully protect public health from toxic pesticide exposure.

PSR looks forward to working with you and other Members of Congress to craft pesticide reform legislation more fully protective of public health and the environment.

Thank you.

[The prepared statement of Mr. Schwartz appears at the conclusion of the hearing.]

Mr. STENHOLM [resuming chair]. Mr. Dooley.

Mr. DOOLEY. Yes, just a kind of a broad question. Mr. Feldman, how do you define sustainable agriculture?

Mr. FELDMAN. We are looking at use reduction, pesticide use reduction in context of national goals that move away from pesticide dependency. And that is a complex statement that relies on looking at different commodity groups, commodities and different pest management systems that to the greatest extent possible reduce pesticide reliance or dependency.

Mr. DOOLEY. So am I interpreting your definition of sustainable as being actually more related to reduced use of pesticides than any other factor?

Mr. FELDMAN. Well, we use the term "biointegrated systems." So we are looking at cropping systems and cultural practices and within a commodity group methods of management, management that result in increased fertilization, natural base systems that hopefully prevent diseases, infestations, and conditions that give rise to the need for pesticides.

Now, pesticides may arise as a needed input into that agricultural system, and we acknowledge that. The point, however, is to try to design the system so as to prevent pest problems. And unless that is an element, the element of preventing pest problems, then there will be an inherent or implicit dependency on pesticides in those agricultural systems. So sustainable systems are not implicitly dependent on pesticides, whereas conventional agricultural systems are implicitly dependent on pesticides.

Mr. DOOLEY. What would be your expectation in terms of yields in productivity under a sustainable regime as you would hope that you would see evolve?

Mr. FELDMAN. Well, we actually did a study in 1992 looking at, in Iowa, at corn and soybean yields, in systems, these were weed management systems that didn't rely on pesticides, and found that the yields were competitive with statewide averages in that situation, and that in fact their input costs—so if you look at yields as an issue unto itself, then we saw competitive yields. Or actually, the organizations in Iowa, practical farmers of Iowa, that were looking at production agriculture, looking at the commercial operations in that State. Because we too, Mr. Chairman, are concerned about production agriculture.

And so in that context, the yields were competitive, but I think more interestingly is the fact that when they looked at input costs and overall profitability, they saw the competitiveness there, too, and over time increased profitability.

Mr. DOOLEY. As a farmer, I hope we get there, but my concern is that, if we do not have some utilization of some chemical tools, then it is going to be hard to maintain the level of productivity and level of volume of production that this country provides for the entire world.

There needs to be some caution as we move forward in moving toward what we would hope to be a sustainable model, that we don't in fact end up reducing production here that could thus have international implications, which could have a far more adverse environmental and health impact than what we would hope to see.

Dr. Feldman, you made a comment that early exposure to pesticides has been implicated in several types of childhood cancers and cancers with long latency periods. Is there documentation that

with use according to label or registration that there has been a direct implication?

Excuse me, Mr. Schwartz.

Mr. SCHWARTZ. Well, the National Academy of Sciences' report is—there has been some additional research since then, but that is to our understanding, the best compilation of some of the science that has gone on, in particular with regard to some of the childhood cancers and the longer latency period cancers. And we would be more than glad to provide you with some of the documentation from within that report as far as—

Mr. DOOLEY. So at this time, you are not aware of any specific incidence that a childhood cancer resulted from the use of a particular pesticide that led to the childhood cancers?

Mr. SCHWARTZ. Well, we are not in a position to say—I am not sure, I would have to look through the research to establish whether, for example, as I think you were driving at, whether the pesticide use linked to various childhood cancers was used according to the tolerances or was done according to the regulatory system or was done outside the regulatory system. I would have to go back through the research to see whether that level of discrimination was applied through the research.

Mr. DOOLEY. That is precisely what I am getting at. Because as we talked about with earlier panels, if you look at a threshold of toxicity, and that when you utilize existing testing protocols and maximum tolerated dose, is that there are some levels of use for which there is no increased incidence. And that is where I get concerned when I see statements being made by responsible groups saying that there are implications of cancer resulting from the use of pesticides.

That is a serious concern to all of us, and we would hope that there would be specific documentation that would also show that this was not a result of a misuse of pesticides. Ms. Hinkle, I really appreciate the dialog that we have had over the last couple years on a number of issues related to this, and you make a point in your written comments on alternative pest control strategies and you bring up the situation where there are some instances of a pest developing a resistance to Bt—*Bacillus thuringiensis*.

And we would acknowledge that happens with, natural pest control devices as well as some of the chemical tools that we utilize. But that in fact then argues that you are going to have to have a variety of alternatives to address pest problems. How do we foster a regulatory environment, as well as a financial environment, that allows for the development of some of our biotech products and genetically engineered products that can be used as additional tools and alternatives? And does the Audubon Society support trying to create a regulatory process that promotes the technology and the adoption of products, perhaps a herbicide resistant variety?

Ms. HINKLE. We think that we need to build a knowledge base, upon which the new generation of pesticides can be encouraged, and the research and development and registration of these new generation technologies will get registration.

We think that there needs to be specificity so that a registrant knows which door at EPA he has to go to, what kinds of waivers

he will be entitled to, and what he can expect. And right now, the administration proposal really relies on a conventional model.

They self-certify, they have conditionals modeled after chemicals, they even have an unfunded mandate in the sense that EPA has to perform by certain time lines, and if EPA does not, then there is a rebuttable presumption that it is a reduced-risk pesticide and they will get automatically their pesticide registration.

And this is just the reverse of what we need, because we need to build a solid knowledge base upon which the biotechnologies can proceed, knowing that there is a reduced risk or that these nonconventional chemicals are very specific, host specific, narrow, they will do things that we know what to expect and they should get on the market right away. And many of them won't have to do any of these other long-term tests because of their use.

In regard to resistance, Bt is a natural resource. And if we have resistance to Bt, we are losing a natural resource. And we really shouldn't allow that to happen.

Mr. DOOLEY. With some of the recent actions on a soybean variety that has a resistance to—I can't remember the chemical name, but Roundup is what we use. Would that be a product then that you would then have an expedited registration process for? Because Roundup is obviously one of the safer materials we have out there and the resistant soybean could preclude the use of some more toxic materials, now would you support or would the resistant soybean fit into your safer category? And should we have an expedited registration process for these products?

Ms. HINKLE. Its use might preclude being considered as a really reduced use pesticide. It is because glyphosate, Roundup, is used on so many different crops. And so once it is engineered into all of these various crops, then its use may not go down.

Although I have been told that it will result in 50 percent less use of pesticides overnight. So that if one establishes a target goal of percent reduction, then glyphosate resistant crops will overnight result in a huge reduction in the use of pesticides. And I think that we have to look at the product itself.

Right now, the company does a certain number of tests in the field, and then they automatically get their registration. But the knowledge base isn't necessarily enhanced. And we have to worry—we really have to be concerned with building a knowledge base that will help agriculture to cope with the problems that we are facing.

Mr. DOOLEY. You are not implying that we, or are you, that we should then require a registrant of a—or someone who is trying to provide this in the marketplace, that they should actually then engage in field-based studies to document that there would be a reduction in the—

Ms. HINKLE. No, I am not favoring that.

Mr. DOOLEY. All right, I thank you.

Ms. HINKLE. I just brought it up as an example of how it might meet a different kind of goal.

Mr. STENHOLM. Continuing kind of along the same line, if I were to wear my hat in real life right now, I would display a great amount of anger toward the organizations that you represent and the damage I believe you cause me as a farmer with the positions

that you have taken. But I am not wearing my farmer hat, I am wearing my chairman's hat.

And in that spirit, Mr. Feldman, I appreciate your remarks about the spirit that went into FIFRA in 1988, and I recognize that we have to find that middle ground. And that means that all of us have to give a little bit in order to get legislation. And that is the spirit in which I undertake this action of passing a bill, of recognizing that we do have to find middle ground.

As chairman, one of the things that frustrates me a little bit, Ms. Hinkle, is the fact that you heavily emphasize the necessity of building a knowledge base for biotechnology, but in my opinion you seem to want to totally ignore the knowledge base in the area of pesticides, herbicides, and FIFRA. Not by what you say, but by what you do. Not you, I am talking generically now. I don't want to get personal with anyone.

Let me get at what I am specifically getting at. I mentioned the tabloid TV many times today. You have learned to use that to accomplish your goal, very successfully, and it is done perfectly legally under the constitution of the United States, freedom of speech, individually and collectively, and some of you personally have learned to use this to the maximum degree.

Every time you do, you end up hurting the people I represent. And I don't think you mean to do that. I think you mean to accomplish the goals which you state. But I have observed that you do. And that is a fact, because you don't get at the chemical companies, you don't get at the middleman. You get at the guy that is producing the food. And you also are going to make it difficult to feed the world, if we in fact eliminate technology.

And where I am coming from is when you say we want to build on a knowledge base for biotechnology, I do, too. But I get very frustrated when I face opposition to pesticides and then we turn around and we also face opposition to the creation of alternatives to pesticides, for very good and valid reasons, nobody knows what the result is going to be. Just as with the administration this morning, we ascertained for the record, science cannot tell us definitively today what any either man-made carcinogen or God-made carcinogen really does to the body.

Now, do you agree or disagree with that?

Ms. HINKLE. I believe that you think I am antitechnology.

Mr. STENHOLM. No, I—

Ms. HINKLE. I am not antitechnology, nor do I want to ignore it. I think some people think technology can solve everything, and some basic critical fundamental questions aren't asked that need to be. For example, technology can prolong life way beyond the will of the person whose life is being extended, and now finally we are asking questions, How long should technology be used to extend a life that may not want to be extended?

Mr. STENHOLM. I happen to agree with you totally on that analogy.

Ms. HINKLE. But the analogy means that we need in all cases of technology to ask questions about it. How is it being used? Is it appropriate? And what do we really need to know about it before we can use it? And what we want is more tools for the farmer. And we think that currently farmers are being deprived of the pest con-

trol agents that they really need. For one thing, resistance is occurring rapidly and in many cases, new exotic or nonindigenous pests are coming in that are not controlled with their natural enemies, so they just take over because there is no competition for them in this country. And there are chemicals that are bad actors and need to be removed and some of them will be, one way or another.

Some people think DDT would have been cancelled on its own, because of resistance. Therefore, farmers need more tools. And we think that they need many different kinds, and that is the thrust of my work. I don't think it is different from what you want.

Mr. STENHOLM. I don't either, and I was not referring to you personally. I was referring generically to the panel.

Ms. HINKLE. But I can only speak for what I am working for. I cannot speak for the rest of the world, any more than you can speak for all of Congress.

Mr. SCHWARTZ. If I could just follow up with that. I get the sense from your remarks and from the remarks that some of the other subcommittee members, that there is a sense that there are people out there, whether it is from the public health community or the environmental community, that are out to stick it to the farmers.

Mr. STENHOLM. No, you are not out to do it, but that is what you are doing. You have very admirable goals. I can't disagree with the basic philosophy of what you have all said today. All I am trying to point out is the end result of how you try to reach your goals is having that result. And what I want to try to work out, is how we might in fact overcome that end result?

Mr. SCHWARTZ. I think what we are trying to do is to look at the current system that we have and to inquire of Congress, of the regulating agencies, the industry, and the farmers, we are trying to find out how much better can we do. I think because so much is lacking in terms of information about how much pesticides actually get used in certain context, we don't know how much better we can do. And I think that is what we are trying to establish.

If it turns out that by reducing pesticide use we would have a drastic reduction in crop yield, well, that would be a problem. But I think at this point we don't know how much better we could do. I don't know if we have a good understanding, or as good an understanding as we ought to have, as to how much we could reduce pesticide use, shift away from some of the chemical pesticides toward some of the more sustainable alternatives, without having a reduction in yield.

And I think that is where we—I understand why you are sensitive to the tabloid TV and all that, but I think what we are trying to do is to enter upon a cooperative dialog to find out, with farmers, with the regulators, to find out—we think we can do better. How much better can we do?

Mr. STENHOLM. I know we can do better. And, therefore, I am very sympathetic to that general process of moving ahead. We are talking about tactics. I want to—for my own information and for the record, I want to ascertain from the four of you the question I gave to the administration.

Again, let's relegate it to one area, carcinogens. Based on your scientific knowledge, is there a difference on the human body between God-made carcinogens and man-made carcinogens, based on

your knowledge, personal knowledge and all of the study and the tremendous amount of work that each of you put into this subject; is there a difference?

Mr. WILES. I will agree with Dr. Goldman who earlier stated that if something is tested through valid tests and is shown to be a carcinogen, it is irrelevant whether it is natural or chemical. A carcinogen is a carcinogen. She also made the point, as did Mr. Taylor, that we have tested far fewer natural substances in the same rigorous way that we have tested synthetic chemical substances. A carcinogen is a carcinogen.

Mr. STENHOLM. I would be curious, Mr. Wiles, why you and all of you would not be insisting that we test to the same degree we test pesticides, test these other carcinogens to see if in fact they are true. And if they are, then why we would not be supporting research projects, biotechnological developments, that would breed out of the plants the carcinogenicity.

Why would we not be spending time on that, if they are equal?

Mr. WILES. As a general proposition, I would support that concept. I think the notion is that we have lived throughout the ages with natural carcinogens and then we have synthetic carcinogens or potentially synthetic carcinogens that we are adding to the environment, and there is some concern that we don't want to add new potentially toxic or carcinogenic substances in the food supply. I think that is why research is focused in that area. But we would support research in aflatoxin and the seriousness of those kind of hazards.

Mr. FELDMAN. There is another key distinction here that I think we shouldn't lose sight of. I am not disputing the belief, although I am not sure it is fully tested, that we should be equally concerned with natural and synthetic carcinogens. But in fact we do know that there is a finite unit or finite universe of chemicals out there, synthetic, that we have added to the environment, to the food supply, what have you. And we have done this without fully testing them, whereas we can't define the finite unit of natural carcinogens that might be out there.

Mr. STENHOLM. Are you real sure that we know there is a finite?

Mr. FELDMAN. We know there is a finite unit of synthetic materials that is registered as pesticides.

Mr. STENHOLM. But we do not know there is a finite result of the utilization of those products, do we?

Mr. FELDMAN. Well, as Richard said, we know we are adding a finite number of materials, synthetically derived materials, into the environment, and adding the potential of a whole series of risks, cancer being one of them. What I wanted to get at is having said that, the difference between natural and these synthetically derived materials is that there is a multiplicity of exposure which we don't get with the carcinogen like aflatoxin.

It is discrete to a particular use or exposure pattern, whereas the introduction of a fungicide that may be used on peanuts, captan, EBDC's, affects the human body across different exposure scenarios as NAS points out in the pesticides in the diets of infants and children. You cannot define the discrete exposure. It is out there in the environment, it gets into ground water, it gets into ambient air, it could persist in the environment over periods of time.

And so what you are dealing with is a multiplier factor with synthetic chemicals in particular that you don't have with natural. As a result, if I had my choice of how to invest public dollars to protect the public, I would take the synthetic before the natural.

Mr. STENHOLM. You know, of course, this is the general area, and I read quite a bit on this subject and I am led to believe that the knowledge base suggests that there are no fundamental differences between God-made and man-made carcinogens. That is the preponderance of evidence as the scientific community imperfectly gives to us today.

Now, I believe if I have heard y'all correctly, both the spoken word and all, that you have not disagreed with that, but you have rationalized it a little bit differently than perhaps I would.

Ms. HINKLE. Where we find naturally occurring carcinogens like sassafras and rotenone, then I think the same actions should be taken for naturally occurring carcinogens if they don't have to be—if you don't have to be exposed to them. Patulin is an extremely toxic, naturally occurring carcinogen that is found in peanuts and peanut butter and apples. So that if one isn't careful in making apple cider, you can get quite a big—a double whammy. So I think that there needs to be education about naturally occurring carcinogens.

We don't have enough information. For instance, cabbage, if you eat raw cabbage every day, it tends to promote cancer of the colon. If you eat coleslaw every other day, then it prevents cancer of the colon. We really don't know why. The etiology of cancer remains a mystery. And I think that we need to know more. And this would help the knowledge base. And I just can't see why anyone would be against a knowledge base.

Mr. STENHOLM. No, I am not. That is my whole point. I do agree that we need to expand our knowledge base. But enough of this. I don't want to belabor too many of these points, but I think maybe the schoolchildren all over were relieved to find out that cabbage every day was bad for them. I happen to like it, myself, but not every day. That again is the point.

So often in our testing procedures, there is a lot of scientific knowledge that we don't know, but yet sometimes we all talk about it like we knew it to be absolutely true. That is my only point. We have to be careful stating things specifically, particularly for consumption by the general public, when in our hearts we know that we are not 100 percent sure that what we are saying is the truth. That is my only point.

Ms. HINKLE. Well, some pesticides cause cancer very early in the testing regimen. EDB, Alar, and alachlor cause cancer very early on. So therefore one could draw some assumptions that exposure to such chemicals at an early stage might contribute to cancer of infants and children.

Mr. STENHOLM. And where we have scientific evidence, the bad guys ought to be removed from the market as quickly as humanly possible and we all agree to that. As long as it is based on good sound science, best as we have it, not on the individual opinion of one scientist. One thing that is driving me up the wall, since this is nutrition also, we talked about saccharin today, we are bouncing back and forth like a ping-pong on every individual product that

one test finds has been bad. Now we are finding out that those things that we were told were safer were bad, and it is all based on one study by one scientist. That is not good.

We need a consensus. We need to build a knowledge base. I am agreeing with you, Maureen, more than I am disagreeing, both with your written statement as well as what you are publicly stating. In fact, I would like to believe with all of you. But there are some fine lines in here that really have to be worked out. I want to ask you about whistleblower protection, do you believe that we ought to have whistleblower protection?

Ms. HINKLE. Yes.

Mr. FELDMAN. Yes.

Mr. WILES. Yes.

Mr. SCHWARTZ. Yes.

Mr. STENHOLM. I do, too, but with one fundamental difference from what we normally talk about. It needs to be a two-bladed ax. I don't think we always ought to protect the fellow that perceives that there is a problem out there, if it turns out that there is not a problem, particularly when you use the media.

When you go on the media and say things based on your belief or you get someone that is a whistleblower that has got an ax to grind and he finds out later there was nothing scientifically behind it and damage has been caused, innumerable damage has been caused to producers and consumers, there ought to be a dual responsibility.

Do you agree to that?

Mr. FELDMAN. When there is——

Ms. HINKLE. Aren't there libel laws?

Mr. FELDMAN. Yes, there is nothing to preclude pursuing legal actions.

Mr. STENHOLM. Yes, but here we are getting down to—I am not a lawyer, but this is one of the things that raises the hackles. When we say, aren't there other laws to protect, sure, just take a look at all of the folks that have been damaged because there is not either a case that can be proven or there are not resources there to take it to court and get the end result. And look at the damage that that does.

Sure there are laws to protect it, but you have to have gobs of money or be willing to spend it, just like the apple growers. They had to be willing to spend hundreds of thousands of dollars to bring suit. But so many times we make statements pursuing our goal, that, sure, you could be held liable, but you got to have deep pockets to go after it, and if you happen to be a small producer somewhere, you ain't got the deep pockets.

Ms. HINKLE. If regulation were performing adequately, efficiently, and fairly, we wouldn't need to have whistleblowers blowing their whistle.

Mr. STENHOLM. Yes, but that is a perfect world. We are always going to have bad CEO's, bad companies, folks that are going to rip off the general public. We are not going to get rid of all criminals. We are always going to have lawbreakers. We can take all the guns away from everybody, people are still going to get shot.

Mr. FELDMAN. I think what we are meaning to do is focus on the intent of that as was said earlier in the testimony. The intent real-

ly is to provide for a course of action for people who have been damaged in the workplace or people who perceive a potentially dangerous situation, to pursue that in a manner that attempts to resolve the problem.

And I think the language can be written in a way that allows for that, while not having the negative side effects that you are trying to achieve, because the real purpose here is where workers see a situation that is or could adversely affect human health, that there be an avenue for them to pursue, to correct that situation.

And it may even be a situation that the management wants corrected but isn't aware of and workers are too scared to speak up. So it really is a mechanism and I think we agree on the intent and probably can resolve that.

Mr. STENHOLM. Again, it is always best to solve a problem. What I am getting at, and, you can clearly tell the tabloid TV bugs the hound out of me, because they are not responsible. And when you feed them with information that you believe is correct that has the kind of results that you now told me you don't want to see, it creates a problem that bugs me. Maybe that is a bad analogy, a pesticide.

Mr. FELDMAN. And you understand, we have had these conversations, you understand the frustration on this side, where we are trying to work with the regulatory process and a standard of safety that most in the public interest community feel is unprotective of public health, it is very difficult, having worked with that procedure for so long, to not have an opportunity to get directly to people in the marketplace so that they can make informed decisions. I think that is what the environmental and public interest community is about, trying to get information to the community of people out there so that they can make an informed choice.

What does an EPA registration mean? What does it mean that a pesticide is registered by EPA? What is an inert ingredient? What right do you have to know to make full and complete decisions that are informed? And this is where I think you are right, it can be interpreted in ways that have or create economic dislocation for certain farmers. And obviously that is not the intent.

The good get caught up with the bad. But right now, I don't believe personally that consumers in this country, school board administrators or school administrators, people responsible for parks and recreations, generally those who are in responsible positions for pest management have full and adequate information with which to make informed choices. And I should add, of course, farmers to that list.

Ms. HINKLE. Mr. Stenholm—

Mr. STENHOLM. And I think we would add all four of you at that table to that same list, and I would agree with you. Does everybody there agree with that statement?

Let the record show all but one have agreed.

Ms. HINKLE. Well, there is supposed to be fairness in communication, so if you think it is all only one way, that it is only farmers that are being nailed, then write to the FCC and tell them that farmers deserve equal time.

Mr. STENHOLM. No, ma'am, let me show you another part of where I am coming from. And this will be my last comment. But

as chairman of this subcommittee, Department Operations and Nutrition, we have the responsibility of oversight of technology, which is the subject of today's hearing.

We also have the responsibility of oversight of nutrition. And in this dual responsibility, I have had to put on a new hat, and I have made this observation many times. The first 14 years I served in the Congress, I did everything to avoid serving on the food stamp subcommittee. It is not a popular subcommittee back home. But this Congress, not only did I ask to serve on it, I asked to be the chairman, because I see a direct relationship between the direction that we were going on technology and hunger and nutrition, of which we all agree, there are direct relationships.

If you want to deal with the crime problem, you had better deal with the child in the woman and see that they get a healthy start. If you want to worry about the cost of health on down the line and health care reform, you had better take a good look at nutrition and what we are doing to the body.

I have observed one thing in my new clientele that I am getting lobbied by and lobbying, the hunger community. If you are a poor person in this country or in the world, you could care less whether we dot the "i" and cross the "t" as to whether our food supply is 98 percent safe or 98.1 or 98.2. They are interested in quantity.

And where I am coming from, I don't want us to be so caught up in the pursuit of very important goals that we foul up the technological advances that have provided the most abundant food supply. And I am worried about that. And I hope you worry a little bit about that, because if you are ultimately successful in winning the war on the tabloid TV by—and again, I don't want to make this personal, because I am just talking generically now. We are going to lose technological advancement in this country.

The minor-use question is very obvious. Companies will not spend money developing new technologies if they are going to have to spend years and months waiting on somebody to decide whether the knowledge base is great enough in order to let the product go on the market. That is a given economic fact.

So many times we agree to the objectives, but our strategy turns out to be the worst thing that we can do. And that is where I want us to try to come from as we seek this illusive compromise, is try to find some middle ground in which we can allow technology in this country to go on, just like Mr. Volkmer is concerned about his job base. We can, by pursuing the ultimate objective that perhaps we all might want, we could eliminate technology in this country and it will move somewhere else. And I don't have any doubt whatsoever that some other country and their congressmen and women will be able to say 20 years from now or 30 years from now, aren't we blessed to live in a country that has the most abundant food supply, the best quality of food, the safest food supply at the lowest cost of any other country in the world? And that is us today. But it is not necessarily going to be us tomorrow. And so that is kind of where I am coming from, so you understand.

I don't want an adversarial relationship between any of you. But if you want one, I will give it to you. You don't want an adversarial relationship, but you tell me if you want one, we will give it to you.

Somewhere in between, we have to sit down as reasonable people and agree on the direction we need to go.

And that, Mr. Feldman, is what you said a moment ago with 1988, that is where we want to be in 1994. But I hope something of what I said made some sense and hadn't just irritated the heck out of you today. And I hope what I have said indicates my sincere desire to work with you, because you have tremendous powers. And many of my farmer friends, F-A-R-M-E-R, choose to ignore the powers you have, get mad at you, throw rocks at you, do all of those things, that doesn't work. But you have the power to destroy the food producing industry in this country.

Ms. HINKLE. We don't want to do that.

Mr. STENHOLM. You have the power to do it, and you are successfully doing it through the utilization of tabloid TV. It is happening. I wish it weren't. I wished I was wrong. But I am seeing it happen. Why? Because jobs are beginning to leave America. We cannot develop the alternatives because we cannot get an agreement on what the rules and regulations are to get a product approved.

I have had small businesses in my community who are very interested in biotechnology come in and throw up their hands in exasperation because they cannot get approval by any Government agency for developing alternatives to pesticides. That's the situation we have. End of sermon.

Thank you very much for your participation. We truly extend to you the same not only offer, but request that you roll up your sleeves with this subcommittee, with our staffs, to try to put together a bill that we can in fact move forward with and achieve the goals that you have testified for here today. Thank you very much.

I call panel 4. On this panel we have Ms. Duggan, Mr. Vroom, Mr. Ziller, and Mr. Gullickson.

STATEMENT OF JUANITA DUGGAN, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION

Ms. DUGGAN. Good afternoon, Mr. Chairman. I am Juanita Duggan, senior vice president for government affairs for the National Food Processors Association. We appreciate the opportunity to address the important topic of pesticide regulation and food safety.

We commend the chairman's leadership in providing a forum for discussing the critical food safety and pesticide policy choices facing the EPA. We strongly support programs to develop economical alternatives to pesticides and the food processing industry is making concerted efforts to develop alternative pest control techniques. However, we note that with even such ongoing efforts, responsible use of pesticides will continue to be necessary for the production of an adequate, wholesome, and nutritious food supply.

NFPA supports statutory changes to establish a uniform negligible risk standard for pesticide tolerances in raw and processed foods, and to give EPA sufficient authority to take into account the best available scientific information in making tolerance decisions.

The administration has now released its own legislative proposals for pesticide reform and the focus of my testimony will be to explain why we support other approaches. The administration has

argued that immediate legislative action is needed to avoid the potential crisis created by the Ninth Circuit Court decision in *Les v. Reilly*, in that unless immediate legislative changes are made, the agency will have no choice but to revoke tolerances for a large number of valuable pesticides, with serious adverse consequences for agriculture and the food industry.

In fact, however, the agency's hands are not tied by *Les v. Reilly*. The potential devastating loss of agricultural pesticides threatened by EPA is not a necessary result of the *Les v. Reilly* decision at all, but rather a result of EPA's concentration and coordination policies. These policies are an EPA invention that have never been properly adopted as regulations and should be abandoned.

In September of 1992, NFPA and other groups filed a petition urging EPA to rescind its concentration and coordination policies and no longer to require separate 409 tolerances for pesticides in processed foods. The NFPA petition urges EPA to follow the language and intent of the flow-through provision of the Federal Food, Drug, and Cosmetic Act, by providing that a pesticide residue in a processed food, when ready to eat, is lawful as long as the residue is not greater than the tolerance for the raw commodity from which the processed food is made.

The petition demonstrates that there is no sound legal or public policy basis for EPA to continue its concentration and coordination policies, and EPA shouldn't be permitted to perpetrate these policies to create an artificial pesticide crisis.

It has been 2 years since the *Les vs. Reilly* decision and 22 months seeing the EPA petitioned to adopt reasonable regulatory policies, and to date, the agency has given us no indication of how they intend to proceed with the vast majority of these chemicals that are now somewhat in doubt.

Back to the administration's bill, after seeing it in legislative form now, NFPA is convinced that it would restrict rather than enhance EPA's ability to apply the best scientific evidence in making tolerance decisions. Moreover, the administration's bill would go far beyond the reform of pesticide tolerance standards and eliminate consideration of pesticide benefits.

It would revise most FIFRA procedures to reduce public participation rights, scientific review requirements, and would grant multiple and unnecessary additional enforcement powers to EPA and FDA and authorize citizen suits in a variety of contexts.

There is no demonstrated need for such a total overhaul of FIFRA. The administration's bill doesn't address another issue of critical importance to the food industry and that is national uniformity of pesticide tolerances. The broad, sweeping amendments in the administration's bill are contrary to the interests of consumers and the food industry and would serve to accelerate the loss of safe and effective minor-use pesticides that are of particular importance to our members.

We have made it clear that we support a uniform, negligible risk standard for pesticide residues in both raw and processed foods, but not at the expense of scientific reason, regulatory order, and consumer welfare. It makes no sense to replace the Delaney clause in the equally rigid and arbitrary standard to create an unnecessary and unworkable multiple tolerance system to superimpose dif-

ferent tolerance reevaluation schedules on top of the FIFRA reregistration process, to abandon consideration of benefits in tolerance decisions, or to impose further data requirement to cost pressures on minor uses.

The administration bill contains many other undesirable features, including a phase-out authority that would empower EPA to limit or prohibit the use of a pesticide on the basis of evidence that is too weak, incomplete, or inconsistent to support a cancellation, the access of any provision to harmonize U.S. pesticide tolerances with international standards, and burdensome fees on the regulated industry.

Although we believe that focused and reasonable legislation is the best way to reform the pesticide tolerance system, the administration's bill is clearly the wrong vehicle.

NFPA strongly supports the Lehman-Bliley-Rowland bill, H.R. 1627, which has broad bipartisan support in the House, and the counterpart in the Senate, S. 1478 introduced by Senators Pryor and Lugar.

We believe these bills provide the best vehicle for pesticide reform and would streamline the pesticide cancellation and suspension processes, establish the consistent negligible risk standards for pesticide tolerances in raw and processed foods, assure appropriate consideration of benefits while providing for uniformity.

Moreover, S. 1478 contains specific provisions which we strongly support and would recommend to the House requiring EPA to implement the recommendations described in the recent NAS study on the report "Pesticides in the Diets of Infants and Children."

The strength of H.R. 1627 and S. 1478 are reflected by the fact that they are endorsed by a broad coalition of food industry organizations including growers, processors, and retailers, and have attracted the support of 222 Members of the House.

In closing, NFPA commends the subcommittee for opening a dialog on pesticide reform and we stand ready to work with the Congress and the administration to develop food safety legislation that will give EPA the tools necessary to reach scientifically defensible tolerance decisions.

We strongly believe that H.R. 1627 should be the model for crafting any such legislation.

Mr. Chairman, we appreciate the efforts of the subcommittee and I would be happy to answer any questions.

[The prepared statement of Ms. Duggan appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Mr. Vroom.

STATEMENT OF JAY J. VROOM, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Mr. VROOM. Thank you, Mr. Chairman and members of the committee.

As time is more precious than usual in this committee room, if you would allow me, I would like to move swiftly to the most important points that we have advanced in our written testimony and some other observations in reaction to some of the earlier testimony.

First, with regard to what we are concerned about in the administration proposal, let me begin by reiterating the National Agricultural Chemicals Association's broad and continuing support for H.R. 1627, the Lehman-Bliley-Rowland bill.

While we still firmly believe that it should include provision for cross-examination and that its proposed cancellation procedure could be further shortened, which could address concerns that Dr. Goldman mentioned this morning.

Overall, H.R. 1627 is a great piece of legislation that represents very substantial compromise from where we are today. In fact it comes toward and it is the middle ground, I believe, that you, Mr. Chairman, have been speaking about all day.

In the administration proposal, we find various concerns with the proposed Delaney reform language which embraces the words, "reasonable certainty of no harm."

This additional language, is supposedly brought forward to bring clarity to a straightforward concept known as a negligible risk. Agriculture can and does strongly object to this subterfuge.

Second, elimination of benefits consideration is a proposal that flies in the very face of the conventional wisdom that the majority of the Congress has recently supported in connection with other environmental legislation.

The benefits must be kept in a better coordinated FIFRA and FFDCA. Benefits consideration in fact, should be, enhanced. Further, EPA has never explained why benefits pose a public health concern.

Third phase-out and phase-down authority is unrealistic and terribly vague. It and the proposed new registration sunset process do not recognize the progress, albeit behind schedule, and the vast public and private investment in the FIFRA reregistration endeavor.

The agency should have given itself some credit, rightly deserved in this regard, by drafting such a proposal with coordination and recognition of the incredible investment already 5 years down the road.

Some other points enumerated throughout much of the testimony that you have heard today: The label call-in process removes all due process and is a loophole through which you would drive virtually all of agriculture out of business.

Tolerances for inerts and metabolites fly in the face of a system that works quite well today. It could use additional refinement, but not a total abandonment.

Separate tolerances has been addressed extensively in other testimony today. EPA has yet to explain why we need to get to numbers that further confuse the public and make commerce virtually impossible. The lack of uniform national tolerances is an effort to avoid greater systemization of the regulatory process in this country that is an opportunity within the next revision of the law, and further, to divide and conquer efforts of those who are opposed to use of technology in agriculture.

Rhetoric we have heard repeatedly from the Clinton administration about their proposal is, it suggests that theirs is a health-based approach, leaving, I think, a very major inference that the current system is not health based.

We have on record billions of dollars of investment from our member companies completing more than 120 separate tests on each compound that we have to complete and provide the data to the agency to get that product to the marketplace, plus additional margins of safety of tenfold to a hundredfold on top of tolerances established based on the scientific tests. That I think says very clearly that today's system is health based.

Yes, it can be improved. H.R. 1627 includes many of the improvements that science recognizes could be brought forward, but the suggestion from the Clinton administration rhetoric that today's system is not health based is patently unfair. Agriculture and food consumers deserve a complete and public correction from EPA to set the record straight.

There are a lot of things that EPA could do within current authority and existing law to extricate itself from the massive administrative challenges and give agriculture some needed relief. The NFPA petition that Juanita Duggan mentioned is important. EPA can rescind the policy of inaction by abandoning outdated policies, including the definition of raw and processed foods; implementing the flow-through and ready-to-eat provisions that are already provided in the current food, drug, and cosmetic law language; and stop regulating on the basis of exaggerated risks; drop the mandatory use of MTD and other high-dose testing when it doesn't make any sense; respond to the objections and grant the stay and hearing requests sought by registrants and NACA in the *Les v. Reilly* tolerance revocation action. Not is the request being ignored, but EPA is going in the other direction, as Dr. Goldman announced this morning.

Also to rescind the current section 18, quote, appearances, unquote, restriction policy or make it applicable only to those products that have, in fact, been proven to be prohibited by Delaney.

Earlier this morning, Congresswoman McKinney raised a question that was answered by the administration witnesses with regard to an unnamed pesticide used on peanuts imported to the United States. I would very much like to find out more about these concerns. I am sorry that Congresswoman McKinney is not here. I would like to know what that pesticide is and where those peanuts are coming from.

Earlier today Dr. Goldman said that there is no requirement in the law for manufacturers of unregistered exported products to provide FDA with an analytical method of detection.

Although that may be technically correct, since 1992 NACA and its member companies have been complying with a voluntary agreement with FDA to provide an analytical method of detection for products that we are exporting from the United States that are not registered here; information on where those products are sold; and on what crops we anticipate those compounds would be used—essentially to help the FDA in looking for potential illegal residues.

So that is the rest of the story on one little corner on all of the discussion here today.

Finally, Mr. Chairman, let me just point out that many of us, are troubled by the tabloid television treatment of agriculture and many of us saw the recent "48 Hours" broadcast that featured one of the witnesses on the previous panel. You may recall that "48

Hours" and CBS went to Columbus, Ohio and followed four families around the grocery store and bought what they selected and had it analyzed in the laboratory. They then used that information which indicated that there were pesticide residues in the foods all within legal tolerances, that those four families were buying, to scare those people on camera in a subsequent interview opportunity.

One of the witnesses on the previous panel was videotaped reading that information and causing that young mother to break into tears. We have followed up at NACA with CBS and they have refused to tell us who the laboratory was or to give us the data. I can only suspicion whether they are keeping the information.

[The prepared statement of Mr. Vroom appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Dr. Ziller.

STATEMENT OF STEPHEN ZILLER, VICE PRESIDENT, SCIENCE AND TECHNOLOGY, GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. ZILLER. Mr. Chairman, and members of the subcommittee I am Dr. Stephen Ziller, vice president of science and technology at the Grocery Manufacturers of America.

GMA appreciates the long and constructive efforts of this subcommittee and others in seeking to bring about reform of the Nation's food safety laws, particularly as they relate to the approval of pesticides for use in agricultural crops and the establishment of tolerances for pesticide residues that may remain on raw agricultural commodities or in processed foods.

The time has come for the Nation's food safety laws to be modernized. For nearly two decades, GMA has supported efforts to do this. That support, however, has been conditioned upon the inclusion in the law of provisions that would strike an appropriate balance between preserving an abundant and wholesome food supply and the protection of consumers against unsafe pesticide residues.

The administration's legislative proposal misses the mark and has a number of fundamental flaws. It is a step backwards:

First, the national uniformity issue: If we are going to modernize the food safety law, the very best scientific judgments must apply uniformly across the country to protect all consumers. The administration's proposal is noticeably silent on this critical issue.

Safety decisions must be made uniformly. Without that, it makes no sense to proceed. Otherwise, States may issue a host of differing tolerations, warning label requirements or other legislation on pesticide residues in food products.

Risk standard: Although the administration supports replacing the antiquated approach of the Delaney clause, the net effect would be just as bad. The EPA should be allowed to exercise its independent scientific judgment in determining a workable definition of negligible risk and appropriate safety factors and not have their hands tied.

Although they claim their proposal is progress, in fact, it is not.

Consideration of benefits: Pesticides are highly important to the production of food in this country. These chemicals indirectly promote public health by controlling disease and damaged food, there-

by providing nutrition and affordable food for American consumers. Indeed, the National Academy of Sciences has recognized the benefits of pesticides are an important consideration in tolerance setting.

The administration's proposal, however, would all but eliminate the consideration of benefits derived from pesticide use in establishing tolerances for residues. The administration's bill does not allow consideration of "an adequate, wholesome, or economical food supply" as a benefit.

As a practical matter, few benefits would qualify for this very narrow definition.

At the moment, when every public health organization in the country is advising consumers to increase their consumption of fruits and vegetables the administration's proposal threatens to raise prices without providing any significant increase in public health protection.

This proposal makes no scientific sense and we respectfully urge Congress to reject it.

Multiple tolerances: The administration's proposal would authorize EPA to establish separate tolerances for a particular pesticide at each stage of a food's change in production or marketing, including at the point of harvest, after processing, and at the retail level.

This invites administrative chaos both in terms of setting the tolerances in the first place and especially in their enforcement.

Enforcement provisions: For the last several years, there has been considerable debate about the adequacy of EPA's and FDA's authority to enforce the pesticide-related food safety provisions of the law. Typically, the agencies have argued for more powers, but have failed to demonstrate why their existing authority is not sufficient to enable them to do their job.

As a result, Congress has consistently rejected the agency's demands. The administration's proposed legislation, purporting only to modernize the food safety laws, seeks to expand EPA and FDA enforcement authority as well, through the back door. This apparent last minute addition of nongermane items to this proposal complicates this issue.

In conclusion, a consensus has emerged. We recommend this committee begin immediately to mark up a bill that over a majority of the House, 222 Members, have already agreed is the best approach, the Lehman-Bliley-Rowland bill, H.R. 1627.

The Senate companion, S. 1478, the Pryor-Lugar measure, also enjoys strong bipartisan support. These bills apply the best science, they specifically address the needs of infants and children, and they establish a national food safety system. They should be enacted into law.

GMA looks forward to continuing to work with the Congress in the development of sound food safety policy and we thank you for this opportunity to participate in today's session.

[The prepared statement of Ziller appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Mr. Gullickson.

**STATEMENT OF WILLIAM D. GULLICKSON, JR., CHAIRMAN,
BOARD OF DIRECTORS, CHEMICAL PRODUCERS AND DIS-
TRIBUTORS ASSOCIATION, ACCOMPANIED BY WARREN E.
STICKLE, PRESIDENT**

Mr. GULLICKSON. Thank you Mr. Chairman. I am Bill Gullickson, president of McLaughlin, Gormley & King Company in Minneapolis, Minnesota and I am here in my capacity as the chairman of the board of directors of the Chemical Producers and Distributors Association. Accompanying me is Dr. Warren Stickle, the president of CPDA.

We are delighted to have the opportunity to appear before the members of the House Subcommittee on Department Operations and Nutrition.

CPDA is a voluntary, nonprofit membership association consisting of 90 member companies engaged in the manufacture, formulation, distribution and sale of some 3.5 billion dollars' worth of products used on food, feed, and fiber crops, lawn, garden, and turf care and for the control of disease vector pests.

We comment here specifically on some of the administration's proposals in detail. Their fee increase, and lack of benefits consideration; the Delaney fix, which we believe is properly addressed in H.R. 1627; public health pesticides; and the draft legislation being put forward by the antimicrobial industry coalition.

We at CPDA are adamantly opposed to the creation of any additional pesticide fee authorities at this time.

Appearing before a joint House-Senate congressional committee hearing on September 22, administration officials estimated that the current reregistration shortfall was \$20 million. Dr. Goldman seemed to reiterate that this morning.

Now, however, it appears that fee provisions in H.R. 4329 will generate in excess of \$60 million in additional fees. CPDA asks that the subcommittee take a closer look at the numbers.

In testimony presented before this subcommittee last year, the Chemical Specialties Manufacturers Association recommended that EPA contract with appropriate outside management personnel to conduct a thorough examination of the registration and reregistration process.

CPDA agrees with CSMA. We support the initiation of a outside review of the OPP, especially in advance of massive new additional fees.

Like all other Federal agencies, EPA is attempting to reinvent government seeking ways to streamline its operations. EPA needs to do more with less resources.

We at CPDA believe that the results of this streamlined process receive thorough evaluation before the necessity for additional EPA resources is even discussed.

Further, CPDA does not believe that an extension of maintenance fees to 1999 is appropriate in 1994. We want to see what impact the various streamlining reforms have on OPP activities and resources.

In the area of benefits, CPDA believes the Delaney clause zero-risk standard is no longer scientifically justified and is virtually impossible to achieve. We don't believe that the administration's pro-

posed health-based tolerance standards which ignore benefits evaluation will satisfactorily solve the Delaney problem.

The FFDCa can be amended in a simple manner to restate the flexible concept of negligible risk, a concept which EPA has long supported. When setting permissible tolerances for pesticides in processed food, a strict health-based standard as proposed by the administration will likely cause the revocation of tolerances which do not pose a real health threat to the American public and will cause the Nation's food supply to be significantly more expensive, if not disrupted.

In the area of Delaney, EPA has stated that the Ninth Circuit Court of Appeals decision in *Les v. Reilly* does not reflect good public policy or good science policy and that the pesticides subject to Delaney pose only negligible risk to public health. But EPA has failed to implement administrative changes which would mitigate the adverse effects of Delaney on agriculture and the Nation's food supply.

Despite two years of deliberation, the agency has failed to respond to the NFPA's administrative petition to decouple section 408 tolerances from section 409 tolerances. The decoupling from section 408 and section 409 tolerances represents the exercise of sound scientific and legal practice by EPA. EPA can accomplish the same administratively without legislative intervention. We at CPDA strongly support H.R. 1627.

The bill creates a single negligible risk standard for tolerances for pesticide residues in raw commodities and processed food. EPA will have responsibility for defining negligible risk in light of evolving science, taking into account different routes of exposure to a pesticide and sensitivities of population subgroups. EPA is then required, where reliable data are available, to calculate the dietary risk to food consumers of the pesticide on the basis of percent of food actually treated with the pesticide and actual residue levels of the pesticide that occur in food.

We at CPDA respectfully urge this subcommittee to markup a FIFRA bill as soon as possible. We strongly support the LBR bill, H.R. 1627 for its treatment of Delaney as well as cancellation and suspension. We support Chairman de la Garza's minor-use bill, H.R. 967 except for the provisions on 10 years of exclusivity.

We strongly support the yet to be introduced antimicrobial bill dealing with certification of me too registrations and labeling reform. We strongly support fix the registration process so that products can be handled in an efficient, effective and expedited manner.

We support portions of H.R. 4329 and H.R. 4362 the administration's legislation to amend FIFRA and FFDC, especially the public health provisions.

We thank you, Mr. Chairman, for the opportunity to present our views.

[The prepared statement of Mr. Gullickson appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Mr. Stickle, do you have additional comments?

Mr. STICKLE. The only thing I would like to add, Mr. Chairman, is that we want to commend Congressman Dooley and Congressman Herger for having introduced the public health pesticide bill.

We really think that goes a long way toward addressing some of those important vectors that carry disease.

We really want to commend them and commend to the subcommittee that if at any point in time the subcommittee begins the markup of legislation dealing with FIFRA, whether it is a large bill or quote, a small bill, we strongly recommend the inclusion of the Dooley-Herger bill in that mix of amendments.

Thank you very much.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Thank you, Mr. Chairman.

I guess maybe, Mr. Vroom, you could respond to this. All of you commented on the double tolerance standards, section 408 and section 409.

I am curious about other countries, do they have similar double tolerances? Are there other models out there that are utilizing a double tolerance?

Mr. VROOM. I think universally you find that a single standard number in the developed world is the basic uniform approach. If you go look at what could be gained theoretically from having multiple tolerances, there is a study that assessed the health impact of lowering all tolerances in California by a factor of two.

The study reported that the effect on human health would be relatively minimal. Basically by taking the CDFA annualized data from sampling of food and pesticide residues that is conducted annually in California, compliance with tolerances, if they were cut in half, would basically only go from 98.5 to 97.5.

In other words, the violation rate for pesticides would increase from 1.5 to 2.5 percent, virtually statistically insignificant change.

The administration's proposal would be a wholesale change—something that would be possibly two, three, or more stages of individual tolerances for every particular compound. I can't see that there would be any significant health gain further.

This study was conducted by Dr. Carl Winter and was published about a year ago and we would be happy to get a copy of that to you.

Mr. DOOLEY. Ms. Duggan, on the 409 tolerances or the potential to be set at different points in the distribution or the processing, again—and I don't have the understanding of the administration proposal to the degree that I would like—but from your understanding and evaluation of it, what is going to trigger when there would be the need for a new tolerance or an additional tolerance post the 408 raw product?

Ms. DUGGAN. Well, it is a very confusing system that they have set out. And they just recently put a proposal together that tried to explain it further and I think a lot of us are still trying to make heads or tails of that document. But we are baffled by how a multiple tolerance system would in any way increase the safety of the Federal supply.

I think Congresswoman Lambert sort of hit the nail on the head when she asked her question. We would be trying to collapse what are two inconsistent standards now in the law to a single uniform standard only to do the risk assessment and then set a series of tolerances at different points along the chain. That is not something that is going to enhance consumer confidence.

We think it will be very confusing. What triggers there are, I cannot add to that for you right now. I would probably have to provide that for the record. But it seems that because there are—Dr. Goldman answered a question where she said there might be some instances where the farmgate tolerance was above the health-based standard and then you would have to set separate tolerances so that people would think what is on their dinner plate was below the health-based standard.

Our point is that we should move to a single standard, set tolerances and set one enforceable tolerance that is safe so that everything whether or not it normally has residues below that level or not, everybody has confidence that we have safe food, and then if tolerances are set as though pesticides are reregistered with modern data sets, if those tolerances are lowered that is fine, but let's get on with the business of setting one tolerance that is safe under one single uniform safety standard in the law.

Not to mention the fact that it doesn't seem to make much scientific sense or have any relationship to safety, but the enforcement aspect for FDA of enforcing different tolerances at different points in the food distribution chain is going to be very resource intensive and I think we have all understood that FDA is an underfunded agency with mandates that they cannot meet now.

So we are very concerned that this would be a completely onerous requirement for FDA from an enforcement standpoint. We also understand that they are talking about after the farmgate tolerance for commodities like tomatoes that they would have different tolerances at different points along the line for every food product, so you would have tolerances for paste, sauce, puree, and salsas.

So you are not talking about dual tolerances; you are talking about many tolerances for the same product.

Mr. DOOLEY. On a different issue, and this is almost from a producer's standpoint, what would be the industry response, if you have a reregistration and basically reevaluation process after 15 years, as I understand is in the bill?

My concern is with an expiration of a patent and right of exclusivity, what jeopardy does that create, in changing the financial dynamic on whether or not a company would in fact see the financial benefits to reregistering? How serious is that from a standpoint—because a lot of those products will become generic and who is then going to be vested with the responsibility?

Obviously this is something we are concerned with in California with the minor-use issue which has similar problems. Is this a real threat?

Mr. VROOM. I think that it is a very significant threat in its least onerous rendition, just adding additional uncertainty in the context of all the other standards that the Clinton proposal has laid out. Not just the fact registration in its entirety every 15 years, but having to be phased out or phased down also.

But then in the context of a lot of few standards that are highly vague and the description of what they have laid out in their legislative proposal. Right now, we have seen diminished incentive to invest as the amount of time to get a new product to the market continues to grow and the commensurate cost goes up.

The patent question is one that the industry has agreed, between the proprietary-based research companies and the generics, that we should not debate in the current context of more important and larger environmental issues. So that is fixed, given in terms of the economic dynamics.

Mr. DOOLEY. I think most in the industry, and I think a lot of us would agree that we have to improve upon the cancellation process that we have now. But, I mean, as an alternative to the arbitrary 15-year reregistration, what is the proposed trigger that we ought to have? Because there are going to be some products that we ought to reevaluate.

Mr. VROOM. I think all of us in the food chain coalition have agreed that conceptually at the end of the current FIFRA mandate and reregistration process that we likely will be looking at some kind of a regular process by which we can assure the public that current scientific standard is being evaluated and that testing is ongoing where appropriate and necessary. But we don't think it is reasonable to telescope ahead today and say it ought to be 15 years.

We ought to learn from the current reregistration process that we are investing in today. Probably around the turn of the century, 2 or 3 years behind what the schedule was laid out to be in 1988, but still a reasonable target to hit.

Let's find out what we know then, instead of saying, "Well, 15 years is the magic numbers."

Mr. STICKLE. Between now and the year 2000 or 2005, the agency has basic FIFRA authority to call in data on 32(c)(b) if they feel they need any additional testing or if they have additional concern about a particular product or pesticide they have existing authority to basically address that issue, both in the short term as well as in the long term.

Mr. STENHOLM. The administration did not make a recommendation concerning uniform tolerance. How important is that to the food industry?

Ms. DUGGAN. Very important. From NFPA's point of view, and I think I can speak for the whole food chain coalition that has been highlighted as one of the central features of the Lehman-Bliley-Rowland bill that merits our support. We have been concerned that Federal Government scientific decisions need to be the law of the land and we have had many instances where there has been an erosion of that confidence.

So we need to have nationally uniform laws that would allow, as the Lehman-Bliley-Rowland bill does, for States to petition for a waiver under special local circumstances so it would be balanced between what any particular location might need. Safe is safe. Safe in Massachusetts is safe in California.

Mr. STENHOLM. Dr. Ziller.

Mr. ZILLER. Yes, I agree with what Juanita said and to take it further, it also is going to be very important to have rules that are consistent and uniform in the United States to help us from painting ourselves in the corner on international trade.

I think the consistency of pesticide rules is very important if in fact we abide by the general principle that Juanita mentions which is basing them on sound science, that sound science is usually

going to be the same throughout the United States and there is rare justification to have any different tolerances that are needed in other States or countries.

Mr. VROOM. In fact, Mr. Chairman, I might observe that the Clinton administration might be silent on this question in their legislative proposal but they are investing significant resources in trying to promote and reach agreement on international harmonization of pesticide standards through the organization of economic cooperation and development.

So perhaps they have made a statement that could be read into support of that provision in the Lehman-Bliley-Rowland bill.

Mr. STICKLE. As far as national uniformity is concerned, we think it is important whether you are producing minor-use crops or major crops it is really important so that you have a uniform national system, otherwise we take not a step into the 21st century, but a step back into the 19th century.

Before we had a Constitution we had the Articles of Confederation in which individual States had trade barriers against each other and it impeded commerce between the States. We don't need to go to the 18th century. We need to go to the 21st century. We need a national uniformity system.

Mr. STENHOLM. How important is international uniformity?

Ms. DUGGAN. I would say that that provision is important, although it is basically trying to put a burden on EPA to justify when, in fact, they do deviate from an international standard. I mean that provision in Lehman-Bliley-Rowland does not require that our maximum residue levels be consistent, but when they are different, that they simply be required to justify that through a notice in the Federal Register.

Mr. VROOM. I think it goes right to the bottom line of minor use and that entire crisis. The resources that registrant companies put against developing residue data and defending individual tolerances for specific crops can either be replicated 50 times across 50 States potentially without a national uniformity provision in whatever Congress decides to do with the FFDCA provisions or they can be harmonized to the point where we only need generally one set of those resources in the United States, and then taken even further internationally. Any that can be made to harmonize tolerance levels at scientifically defensible agreed levels among developed countries reduces the number of times that the same tests have to be replicated with very few minor changes, but the same total cost.

So you have a lower overall cost per tolerance, and the resources available to do more tolerance support for eventually minor-use crops that today are falling off the table.

Mr. STENHOLM. The administration spends several pages of their written testimony describing the process they propose on suspension or cancellation. Mr. Dooley just mentioned there seems to be a lot of agreement on the need of improvement in that area, and in their bill they lay out the various provisions consultation with other agencies, public comment, hearings, notice, et cetera.

Is their proposal fair? If not, why? Mr. Vroom.

Mr. VROOM. We don't believe that it is fair and we object strongly to what they have proposed, not only in the context of their provision under the headlines of cancellation and suspension, which re-

move substantial due process protection, not only for the individual company registrants, but I think for all of agriculture to be able to fairly participate in the process.

They also further complicate that entire process by way of introducing a fairly vague proposal for so-called phase-out/phase down. So there are really more layers and matrixes of regulatory vagary that are created beyond just those specific cancellation and suspension provisions which we think take away an enormous amount of the ability of science to be brought to bear in the hearing process, or the cancellation process if it is done by informal rulemaking.

Mr. STENHOLM. Mr. Gullickson, do you have a comment on that or Mr. Stickle?

Mr. STICKLE. I think one of the important things that we probably all agree on is that the cancellation process that we have seen over the last 10 years has taken too long. That it needs to be expedited and streamlined so that we can deal with those products that are, in fact, bad actors. But in our rush to accomplish that, I think there are some important protections that need to be built in.

If you are trying to build an evidentiary case for a lawsuit or a legal action at some point in time, it is really important that during the process of cancellation that you have the right of cross-examination so that can you build the record and you can test the facts and the figures that are being presented by the other side. So in that process, I think it is possible to construct a system that is much quicker, is expedited, yet still basically protects the right of the registrant to cross-examine and get the evidentiary base that he might need before proceeding to another level, if he may want to.

Mr. VROOM. There is also the matter of their proposal on label call which can be done essentially by a fiat, by the Administrator, without any advance notice or regulatory process protection. That effectively is presented as something to address minor label changes but really has no kinds of boundaries, or fences, around it and could be used to take virtual cancellation or suspension action against a product without any kinds of protections or fences.

Mr. STENHOLM. Are there any areas of the administration's bill that you can support or work with that you would consider to be a good addition to H.R. 1627?

Mr. STICKLE. Mr. Chairman, I would like to suggest two things. First of all, in the area of public health, we really want to commend the Clinton administration for adding in the public health provisions. In that provision they provide for \$12 million in research funds and call for coordination with other Departments. And I think that is an important step that we ought to include and couple that with the Dooley-Herger bill on pesticides and the combination, I think is absolutely excellent.

Second, the other portion of the administration's bill that we strongly support is some of the labeling reform that requires an annual labeling compliance date. We at CPDA and a lot of our small companies have really experienced a long and detailed set of problems with the agency's inconsistency of dealing with labels so we in essence have one part of the agency mandating label changes. We make those changes only to face another series of mandate label changes, so if we had one office that could in fact do that, at

one time of the year, whether it be October or November, we would have not only a one-time, annual labeling problem solved but I think we could address the inefficiencies and inconsistencies in the various labeling areas and try to do it all at one time. This is something that the administration has put forward. This is something that the subcommittee passed back on May 17, 1992, in its en bloc amendment in which it created one office and one labeling date per year. So those are two things that are in the administration bill that I think are good additions.

Ms. DUGGAN. From our point of view, there are several. And in principle, the need to streamline cancellation is one strong area of agreement with the administration. I think we are going to argue about how we do that. We thought that Lehman-Bliley-Rowland really balanced the need for public participation rights and external scientific review and their provision limits that greatly.

But the essential feature of decoupling cancellation from suspension we agree with, as we do with removal of the adjudicatory hearing. We also, I think, could support their IPM proposals and their minor-use proposals and the requirement for collection of actual pesticide use data.

It is important to remember, that most of the features in the administration's bill are new authorities and new features of law that do not exist now and many of the features of Lehman-Bliley-Rowland that the food chain coalition supports so strongly are current practices within the agency that we are seeking to codify to maintain discretion, to keep pace with science. And those are two very different approaches.

We differ with the administration on the scope of what is necessary to correct what we believe is a Delaney clause problem, and what they believe is a FIFRA authority problem, so we are going to disagree on the scope of this, I think.

Mr. VROOM. A couple of additional thoughts, conceptually the fact that the administration's proposal embraces a single standard for raw and processed food tolerances I think is very sound and common ground principle that we agree with. Also conceptually the fact that they are striving to try to find ways to streamline the overall regulatory process, in particular with regard to new product registration so that we can get new products to the market faster, I think is good for agriculture, good for consumers, and certainly good for our members.

Mr. STENHOLM. Dr. Ziller.

Mr. ZILLER. I agree with the comments of the other participants on the panel. I think that certainly their attempts to replace Delaney are somewhat misplaced. The pipeline provisions and their statement of it is not as clear as it is in the Lehman-Bliley-Rowland bill. Certainly, fostering of IPM is a good feature in their bill. And I presume that there was an intent at some point to combine the separate minor-use registration bill with Lehman-Bliley. That certainly is a factor in the administration bill which is a positive feature. And then the requirement for the collection of pesticide use data of course will continue to enable people to make more accurate risk assessments and allow tolerances to be set which will allow the maximum safe usage in agricultural commodities. Those are the features that I think are positive but not quite right in the ad-

ministration's bill but certainly should be in the final bill that would be passed by Congress.

Mr. STENHOLM. Thank you all very much. We appreciate your testimony today and look forward to working with you as we develop the legislation.

We call panel 5. Witnesses on panel 5 are, Mr. Engel, Mr. Borman, Mr. Pflug, and Mr. Stickle. Based on all the witnesses that we have heard thus far, it seems that the proper instructions for the subcommittee staff is to take H.R. 1627, use that for the markup vehicle, take as many areas of the administration's proposal that we can, improve upon them, plus any other additions and suggestions in that legislation that will in fact make it more acceptable. So, all witnesses that have testified ought to think of using that as your guidepost as to how in fact we proceed.

Proceed, Mr. Engel.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

Mr. ENGEL. Good afternoon, Mr. Chairman. My name is Ralph Engel. I am president of the Chemical Specialties Manufacturers Association. Specifically, CSMA represents the nonagricultural pesticide industry and our testimony today focuses on three areas, a piece of the Clinton proposal, antimicrobial products, and other issues affecting the pesticide registration process.

At the outset, I want to note that the Clinton administration has expended considerable effort in assembling a comprehensive FIFRA and FFDCA reform package. It has long been clear to all of us in this room that there are no political winners who will emerge from this debate. There are difficult public policy questions addressed in this package and the administration's willingness to engage these issues is to be recognized. Having said that, however, our industry cannot support the legislation and feels that it is not the balanced "middle of the road" proposal that its proponents would have you believe.

Accordingly we have some serious concerns that need to be addressed. The administration has essentially proposed the phase out and elimination of benefits considerations in registration, suspension, and cancellation decisions over a period of 10 years. FIFRA is the last major environmental statute which provides for a risk/benefit standard. Flexible consideration of benefits in these decisions is essential. In fact, an analysis of benefits of such products as antimicrobials which provide health benefits is a legitimate and important consideration which must be preserved in the regulatory process.

The administration's proposed elimination of benefits consideration is inconsistent with the fundamental goals of its own Executive Order 12866 regulatory reform which directs Federal agencies to consider the costs and benefits of available regulatory choices and to select approaches that maximize net benefits to society. Specifically, Executive Order 12866 signed by President Clinton on September 30, 1993, requires any agency developing a regulation to: One, assess both the cost and benefits of the intended regulation, and propose and adopt it only if the benefits justify its costs; two, base its decisions on the best reasonably scientific, technical,

and economic information; three, identify and assess alternative forms of regulation; four, avoid duplicative regulations; and five, tailor its regulations to be the least burdensome on society.

We submit that elimination of benefits considerations clearly violates this Executive order and on this basis alone should not be included in any FIFRA legislative package.

Phase down/phase out provisions. This proposal would accelerate the extinction of the FIFRA cancellation process by encouraging EPA to limit or ban the use of a pesticide based upon a diminished scientific threshold. The due process protections under FIFRA's cancellation process must not be eliminated.

With regard to fees that were discussed earlier today, let me simply emphasize once again that this subcommittee and the Congress should withhold assessing any additional fees on registrants or granting any additional fee authority to EPA pending a thorough review of the registration, and reregistration programs. Such a review should include an examination of the funds collected and utilized in both programs thus far and a specific documented accounting of the use of fees collected in previous years.

EPA Assistant Administrator Goldman's recent decision to contract with an outside management consultant to give her an operational assessment of the Office of Prevention, Pesticides and Toxic Substances—OPPTS—is a smart and valuable step in the right direction. That outside management review must contain a serious financial audit component as well. We look forward to working with EPA and the management consultants on this and related issues.

Mr. Chairman, as you know, CSMA has for the past 18 months worked with the Chemical Manufacturers Association—CMA—the Soap and Detergent Association—SDA—the International Sanitary Supply Association—ISSA—and the coalition known as the Antimicrobial Industry Coalition—AIC. We have now visited with most members of this subcommittee and their staffs about the severe problems which plague EPA's pesticide registration program and have put forward a legislative proposal which will streamline antimicrobial registration process without compromising the integrity of the scientific review or public health.

Many of the ideas contained in the AIC legislative proposal in fact are reasonably consistent with the underlying principles of Assistant Administrator Goldman's own streamlining effort now underway at the agency, and we are actively engaged in the dialog with her staff.

The need for this legislation became apparent to us as a result of the unacceptable backlog of antimicrobial applications pending within the agency with little or no chance to evolve within a reasonable time. The extent of the paralysis became evident when it came to light that only eight new antimicrobial active ingredients have been registered by EPA within the last 10 years.

The problem, however, has also extended to end-use products where applications remain locked up within the agency for unreasonable periods of time and the expedited review provisions of the 1988 amendments remain largely dysfunctional. Among the most serious problems within the Office of Pesticide Programs antimicrobial registration process are, one, the inadequate staffing and resources, two the unnecessary repetitive review of staff ac-

tions, three EPA's low priority treatment of antimicrobial applications and, four, shifting data requirements which charge without scientific justification.

The AIC legislative proposal seeks to address these shortcomings by significantly streamlining the registration process through a series of five steps. And I am not going to go into them because of time.

In conclusion, I want to close this testimony, Mr. Chairman, by emphasizing the need for consideration of our suggested changes and inclusion of the antimicrobial registration reform amendments to FIFRA in whatever markup vehicle the subcommittee decides to pursue. We believe that these problems can and need to be addressed in 1994, whether or not comprehensive food safety legislation is completed this year.

I also want to thank you, Mr. Chairman, and the ranking minority member and the subcommittee and its staff for the focus you have brought to the shortcomings of the registration process during the past year. As always, CSMA stands ready to work with the subcommittee and the agency on this issue.

Thank you.

[The prepared statement of Mr. Engel appears at the conclusion of the hearing.]

Mr. DOOLEY [assuming chair]. Thank you, Mr. Engel.

We will now hear from Mr. Earle Borman.

STATEMENT OF EARLE K. BORMAN, MEMBER, BIOCIDES PANEL, CHEMICAL MANUFACTURERS ASSOCIATION

Mr. BORMAN. Thank you.

I work for L&F Products and we manufacture a number of antimicrobial products, including disinfectants and industrial-use biocides, which are regulated under FIFRA. I am speaking here today as a member of the Chemical Manufacturers Association biocides panel, a CMA CHEMSTAR panel composed of such biocide manufacturers. The panel welcomes the opportunity to appear and comment on H.R. 4329.

The first point on any such discussion with our industry, however, is that H.R. 4329 does not solve major existing problems in the current registration program for the antimicrobial industry. And in many cases, will exacerbate them.

The primary flaw in the bill from our perspective is that it is, from beginning to end, a food-use pesticide bill. Our products, while defined as "pesticides," are not generally applied to food or food products. They are intended to prevent or mitigate degradation, fouling, deterioration or inefficiencies caused by microorganisms in manufactured goods, chemical substances and industrial processes or systems, and on surfaces.

They do not require tolerances under either sections 408 or 409 of the FFDCA. Thus, our products simply do not present the risk of dispersal in the environment, the concerns for integrated pest management, or the food tolerance issues which feed the phase-down/phase-out, reduced risk, and export initiatives in this bill.

Our biocide products do present, however, important and significant benefits in the form of extending the useful life of machines, industrial processes, and eliminating the germs that spread dis-

ease. The bottom line for us as an industry is that we have profound difficulty getting our products, useful and beneficial as they are, registered by EPA in any reasonable period of time. That is what needs to be fixed.

We do not need more regulation of our products. We do not need, nor can we tolerate, unlimited additional fees for nonvalue-added Government reviews. We do not need more litigation. We do not need fewer opportunities for rational discussion of applicable science and appropriate risk assessment.

What we do need are registration requirements that are clear, objective and specific. We need a streamlined bureaucratic review process appropriate to the level of risk posed by our products, which differentiates between major and minor actions, and we need incentives for accountability at EPA, which includes incentives to do the job that is required and to do it in a cost-effective and timely manner.

We also in our original comments, oral comments, have comments on the registration renewal process, cancellation provisions and fees, and I will skip over those, but I do want to cover the export provisions.

The biocides panel opposes the application of the export provisions of H.R. 4329 to its products. As previously noted, biocides are not food-use products and, thus, do not present the "circle of poison" issues which appear to be the genesis of the sections included in the bill.

Application of the program designed to address those issues means that the biocide industry will be saddled with a significant bureaucratic and regulatory burden that will provide no commensurate protection for food supplies or foreign workers.

With respect to biocides, there is no demonstrated need nor justification for additional regulatory U.S. controls. Biocides are covered by the U.N. Environmental Programme, UNEP, London Guidelines for the Exchange of Information on Chemicals in International Trade, which provide ample regulation.

The guidelines incorporate the internationally accepted principle of "prior informed consent," the PIC. This system works and is an appropriate tool for biocide export risk management.

The mechanism in H.R. 4329 for allowing export of unregistered pesticides is inappropriate for biocides. Biocides do not have tolerances and due to their highly specialized formulations and low volumes, many biocide formulations are unlikely to be approved for sale in three other countries with developed registration systems.

To conclude, as I began, what biocide manufacturers need are clear and objective registration standards, a streamlined registration process, and accountability.

I thank the committee for the opportunity to comment H.R. 4329, and look forward to further constructive dialog on this very important issue.

Thank you.

[The prepared statement of Mr. Borman appears at the conclusion of the hearing.]

Mr. DOOLEY. Thank you, Mr. Borman.

We will now hear from Dr. Pflug.

STATEMENT OF GERALD R. PFLUG, PRESIDENT, SOAP AND DETERGENT ASSOCIATION

Mr. PFLUG. Mr. Chairman and members of the committee, my name is Gerald R. Pflug, and I am president of the Soap and Detergent Association. The Soap and Detergent Association is a 138-member national trade association, representing the formulators of soaps, detergents, and household cleaning products, and those companies which supply ingredients to the detergent and cleaning products industry.

SDA members include nationally prominent companies as well as smaller, less well known, often family-owned regional companies. And, along with the well-known formulators of highly visible consumer products, SDA members also include the formulators of industrial and institutional products used in hospitals, nursing homes, hotels, restaurants, manufacturing facilities, and public buildings.

The products of SDA have a long history of contributing to the establishment and maintenance of the public and personal health standards to which we have become accustomed. Unfortunately, these standards and their maintenance are often taken for granted in our country today. Clean clothing, bedding, cooking utensils, plates, silverware, kitchen and bedroom fixtures are, in fact, the broad base on which our exceptional standard of public health rests.

The SDA is here today because of its concern for one of the most important contributors to our country's high standard of cleanliness. That is the antimicrobial and disinfectant cleaning products.

Under the Federal Insecticide, Fungicide and Rodenticide Act, antimicrobial and disinfectant cleaning products are regulated as pesticides by the EPA because they are intended for preventing, destroying, or mitigating harmful microorganisms, viruses, and bacteria. Common, well-recognized examples of such products include household bleach—when such claims are made—Lysol disinfecting cleaner, and Comet cleanser. Less well known though equally important are the myriad of I&I disinfectant and sanitizing products used in health care facilities, schools, business establishments, public accommodations, and public buildings.

I am here today on behalf of the SDA antimicrobial/disinfectant product sector, because this beneficial category of products faces a number of regulatory problems which we believe ought to be addressed through reform of FIFRA.

The principal problems of concern are the following: One, the approval process for new active ingredients needs improvement. During one recent 7-year period, no new active antimicrobial agent was approved; two, the process for registering or reregistering products is so cumbersome and attenuated that such processing may require up to 2 years to complete; three, approval of simple label changes may take often as much as 9 months or more; and four, at the State level, the lack of distinction between antimicrobial products and other pesticides has had the tendency to subject antimicrobial and disinfectant products to regulations designed for agricultural pesticides.

The consequence of these regulatory dilemmas has been to impede the development and introduction of safe and efficacious

antimicrobial products in the marketplace. SDA's concerns are not new.

Congress attempted to address some of these and other issues from a regulatory perspective in previous FIFRA amendments. I refer to FIFRA section 25(a)(1), which reads as follows:

"Regulations: The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this subchapter. Such regulations shall take into account the 'differences in the concept and usage between various classes of pesticides and differences in environmental risk and appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.'" Emphasis added.

At this point, however, we believe that more explicit amendments are indicated. If antimicrobial and disinfectant products, as a subset of nonagricultural products, were distinguished under FIFRA and provided a separate regulatory track, we believe that the approval process for these products would be facilitated.

Based on reports by our affected members, it seems that informal structures have already evolved within EPA, along the lines we are proposing. These informal arrangements have, however, proven inadequate to resolve the problems faced by the antimicrobial/disinfectant industry.

Some increased degree of formalization appears to be required in order to institute a more efficient and equitable regulatory process for antimicrobial and disinfectant cleaning products. It seems to us that the establishment of a separate antimicrobial regulatory track would benefit the EPA as well as industry by clarifying products and standards and establishing an effective division of labor within the FIFRA regulatory approval process.

Further, it appears to us that the formalization of some of the discretionary powers currently held by the Administrator are in order, to assure that antimicrobials and disinfectants receive the same degree of attention they need as regulated products. SDA realizes the enormous task currently being undertaken by EPA in the registration of pesticides and reregistration of pesticides.

We also recognize that the agency operates, as do all human enterprises, with finite resources. However, the agency also has a responsibility to see that all its various regulatory communities whose ability to conduct business depend on the agency, receive equitable allocations of regulatory resources.

While priorities may need to be assigned, that assignment ought not to unduly encumber the ability of agency-dependent regulated industries to conduct business.

When I last appeared before the committee on August 2 of last year, I said that I wished that I could offer you a solution to our concerns. I further told you that SDA was working on a proposal with allied groups.

As a member of the Antimicrobial Industry Coalition, SDA has participated in the development of draft language addressing the definitional and regulatory issues which concern it. In the process of developing the draft language, the coalition has met with concerned parties, including the EPA. At an appropriate time, we would look forward to discussing the proposal with the committee.

In summary, the draft language would distinguish antimicrobials from other pesticides by definition as well as refine the regulatory processes for processing certain approval applications, label changes and other matters currently covered by regulation.

The goal of the proposal is to amend the regulatory process in a way which will reduce unnecessary paperwork and delays for both EPA and business both.

Mr. Chairman and members of the committee, this concludes my formal remarks. The SDA appreciates the opportunity to be here today and I would be pleased to answer any questions you might have.

Thank you.

[The prepared statement of Mr. Pflug appears at the conclusion of the hearing.]

Mr. STENHOLM [resuming chair]. Next, Dr. Stickle.

STATEMENT OF WARREN E. STICKLE, LEGISLATIVE CONSULTANT, INTERNATIONAL SANITARY SUPPLY ASSOCIATION

Mr. STICKLE. My name is Warren Stickle and I am the legislative consultant to the International Sanitary Supply Association. ISSA is a nonprofit trade association comprised of over 4,000 members that are located all across the country. They manufacture and distribute a wide spectrum of institutional and industrial cleaning and maintenance products, including antimicrobial products.

ISSA really appreciates the opportunity to be here, Mr. Chairman. We thank you for holding these hearings. We also urge you to markup a FIFRA bill as soon as possible.

This afternoon what I would like to do is to concentrate on four issues: One, the fee proposal in H.R. 4329; two, the labeling call-in, in H.R. 4329, as well as the labeling reform section of the AIC draft legislation; three, I would like to talk about "fast track" certification, that is also included in the AIC draft legislation; and four, I would like to talk just briefly about H.R. 1867, which is the Public Health Pesticide Protection Act, that has been introduced by Congressmen Dooley and Herger.

First of all, concerning fees, ISSA is strongly opposed to the creation of any new additional pesticide fees and the extension of existing maintenance fees as contemplated in H.R. 4329. What we have heard this morning is exactly what we heard back in September of 1993, when the administration testified and said that they were in fact \$20 million short in the reregistration costs.

However, if you look at the legislation, H.R. 4329, you will find that there is about \$62 million in fees included. To begin with, there is a simple \$30 million addition for maintenance fees for 1998 and 1999.

There is \$4 million included in that for a per-product registration fee; and then there is, if I could use the term, a "second time only" active ingredient fee of \$120,000 and \$60,000, which would bring in about 80 percent of what previously was brought in in 1989, or about \$28 million.

If you add the 30, the 4 and the 28, you get 62, and I think there is a significant discrepancy between what the administration has asked for and what they have in fact included in their bill. I think

we need to somehow reconcile the \$62 million figure with the rhetoric of \$20 million.

I would like to make five quick points with regard to fees: First of all, concerning these fees, we need a full accounting from the agency of how much money they have collected, how they have spent the money on the registration, reregistration program, since FIFRA legislation, since the 1988 legislation.

Second, when CSMA spoke last fall, they requested an independent outside audit. I think we ought to really get the results of that audit to find out exactly where things are, prior to making any determination as to what additional fees could be included.

Third, the administration and EPA have just gone through the process of holding 3 days of a workshop here in Arlington, Virginia. Part of that day dealt with a very important aspect, which we really applaud and support, and that is the whole streamlining process that the agency is presently going through.

The net result of that, though, is that the agency has a whole series of proposals in which they are attempting to streamline the registration and reregistration process. Those streamlining proposals will save a significant amount of money and manpower.

So before we determine to put a price tag on the reregistration and registration programs, perhaps we ought to wait and see how they are going to streamline it first.

Fourth, concerning the maintenance fees extension for 1998 and 1999, I think that is a long way off in the future. I think it is premature to address that issue. We are going to probably, Mr. Chairman, be reauthorizing FIFRA prior to those timetables. I think we can address that issue at this point in time.

Fifth, I would note that despite their attempt to extend the maintenance fee provisions, they do not extend the prohibition against registration fees for 1998 and 1999. So in those 2 years, registrants would wind up paying not only a maintenance fee, but also a registration fee as well.

I would like next to comment on the labeling authority in the legislation. I think we strongly support the labeling authority that is in the bill that deals with an annual uniform system of doing labels. We oppose the labeling call-in, data call-in that they have in there, and we strongly support the AIC's section 10 labeling reform. Because what this does is walk through the labeling concerns and I think establishes a well-rounded program for addressing the problems that a lot of small manufacturers have; that is how to take something that takes 15 or 20 minutes or a half an hour, to make a simple label change, and expedite that registration.

If you are looking at improvement in the registration process, ISSA has testified on a number of occasions that the process of registering "me too" products, "me too" antimicrobial products, has gone very slowly. Something that should take 90 days and then another 45 days, is taking 6 months to up to 2 years.

We really need a solution to that and the certification process that is in the AIC draft legislation, which is section 8 of that, we strongly support as a means of not only expediting the registration process, but also of saving the agency a considerable amount of money in processing and eliminating some of the steps that they have to do to process a "me too" product.

Last, we wanted to commend Congressman Dooley for his public health legislation, H.R. 1867, and we want to urge that you include the AIC regulation and the Dooley-Herger legislation in any bill that this subcommittee is going to be marking up. Whether they decide to markup a larger bill or a shorter, smaller bill, that is not the overall comprehensive FIFRA reform bill that we have been talking about today.

Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Stickle appears at the conclusion of the hearing.]

Mr. STENHOLM. I thank each of you.

Any additional comments that you might wish to make that you didn't include in your formal testimony or any statements?

I don't have any specific questions to ask of you, either.

Mr. ENGEL. Mr. Chairman, I neglected to ask that for the record the entire statement be included.

Mr. STENHOLM. Everyone's statements today will be made a part of the complete record.

And we, too, had a lot of excellent suggestions and you heard the general game plan. We look forward to working with you to see if we can accomplish just that.

Thank you very much for your attendance here today.

I call panel 6. Mr. Allen James, Mr. Goldenberg, Mr. Delaney, Mr. Hazeltine, and Mr. Karmol.

The next witness, Mr. Allen James.

STATEMENT OF ALLEN JAMES, EXECUTIVE DIRECTOR, RESPONSIBLE INDUSTRY FOR A SOUND ENVIRONMENT

Mr. JAMES. Good afternoon, Mr. Chairman and members of the subcommittee. It is a pleasure for me to be with you today to represent the members of RISE, Responsible Industry for a Sound Environment.

As this is the first occasion I have had to speak with the subcommittee, I would like to provide you with a short introduction to our association.

RISE is a national trade association of basic ingredient manufacturers, formulators, and distributors of pesticides for the specialty nonfarm market. We were formed about 3 years ago to address the issues of pesticide products for the specialty market, which includes turf and ornamental, structural pest control, and vegetation management. These different segments are lawn care and garden care, golf courses, sod farms, general pest control in and around homes and buildings, public health, nursery and greenhouse operations, roadside and rights-of-way management, and maintenance, and aquatic and forest management.

As you see, our members supply pesticides to a broad array of product users other than traditional food and fiber agriculture. Our products are most often used in urban areas by both professional users and retail consumers.

On behalf of these companies, I would like to thank you for the opportunity to comment on H.R. 4329, and H.R. 4362, the administration's FIFRA and food safety legislation.

I have also provided written testimony which offers more detailed comments on specific proposals contained in these bills. And as you indicated, we also ask that it be entered into the record.

Now, I would like to focus my remarks on four areas of highest concern to our industry. At first, one might think that food tolerances would not be an issue to our members and product users.

However, quite the opposite is the case. If the situation with the Delaney clause is not corrected, many products which are registered for agricultural use will be lost.

Unfortunately, there may not be sufficient nonagricultural markets for these same products to justify continued registration. Especially in light of the many new fees called for in this legislation.

Likewise, the nearly complete loss of pesticide benefits consideration under H.R. 4362 is very disturbing. Valuable products thus lost to agricultural production will again likely be lost to our industry as well.

Our members are equally concerned with provisions relating to label call-in. We all share the goal of risk minimization, but both professional and retail segments of our industry worry that the broad array of changes in labeling, packaging or even product composition, which may be required by EPA if the Administrator determines that risk associated with the use of the pesticide can be reduced, could seriously undermine the lengthy and expensive processes in place to bring these products through registration and to market.

Finally, I will briefly address the issue of integrated pest management, which is strongly endorsed by our members and has been growing in understanding and practice among users of our products. However, as defined in H.R. 4329, IPM fails to recognize the value of synthetic pesticides as an essential component. And by directing Federal agencies to adopt and promote IPM thusly defined, H.R. 4329 creates a legislative preference for biological controls without merit or scientific basis. Agricultural and specialty users, as well as Federal agencies, need a complete arsenal of control methods available to develop effective IPM programs.

For these reasons and others more fully described in our written testimony, RISE cannot support H.R. 4362 or H.R. 4329 as written. But we do support H.R. 1627, the Food Quality Protection Act of 1993.

Thank you very much.

[The prepared statement of Mr. James appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Next, Mr. Goldenberg.

**STATEMENT OF NORMAN GOLDENBERG, PAST PRESIDENT,
NATIONAL PEST CONTROL ASSOCIATION, ACCOMPANIED BY
ROBERT ROSENBERG, DIRECTOR, GOVERNMENT AFFAIRS**

Mr. GOLDENBERG. Thank you, Mr. Chairman and members of the subcommittee.

We appreciate the opportunity to be here today to testify on behalf of the National Pest Control Association.

My name is Norman Goldenberg, I am an entomologist, and I am vice president of government affairs for Terminix International and

TruGreen-Chemlawn. I am accompanied today by Bob Rosenberg, who is director of government affairs for NPCA.

NPCA is a trade association representing over 10,000 companies engaged in structural pest control in the United States and abroad. We render services to homes, businesses, buildings, restaurants, for the control of such pests as cockroaches, termites, ticks, rats, and other vermin.

Many of these insects, rodents, are responsible as vector carriers with such diseases as hantavirus, Lyme disease, and Rocky Mountain Spotted Fever, as well as Salmonella. Additionally, over \$2.5 billion a year in damage is created by termites throughout the United States.

We are concerned with several parts that are not included in the bill before you today. For example, there is an omission on certification standards for commercial pesticide applicators. Current law requires that all applicators of restricted-use pesticides be certified in accordance with FIFRA.

However, an applicator is not required to be certified when he makes or she makes the actual application of the pesticide if it is for a restricted use. Only the supervisor is required to be certified.

Additionally, and more importantly, many building managers, custodians and groundskeepers, apply general-use pesticides, most of the same products that we apply as commercial-certified applicators throughout the United States, in their normal routine, business practices today.

They may subject people in the largest buildings across the country to pesticides without any training or education whatsoever. We are concerned about that, and we want to remind the committee that in the 102d session of Congress, Mr. Rose's Pesticide Safety Improvement Act, H.R. 3742, addressed this issue.

We would like to recommend and urge that the committee adopt language that would require the education, training and certification of all applicators, except for antimicrobials, of course, and homeowners when they apply pesticides on their own specific residential property.

We are concerned about the citizen suits, as has been mentioned by many other people here today. For the most part, the 10,000 companies that are represented by NPCA would be severely affected in this already overly litigious society.

Lawsuits are prevalent everywhere, and many of these businesses would not be around if they were attacked when 50 State legislatures, 50 State regulatory agencies and the Environmental Protection Agency already oversees the activities of structural pest control businesses throughout the United States.

We are concerned that while companies have a responsibility and are insured for that protection of the consumers which we serve, and others, this unnecessary phase of the administration bill, we feel is an aberration in today's society. We also feel that the civil penalties that have been increased in H.R. 4329 are not fair to the businesses of commercial applicators, as well as to farmers.

Mr. STENHOLM. Could I interrupt you?

Could you hold your thought there? I have 4 minutes to vote and nobody to help me this time, so 10-minute recess, I will be back.

[Recess taken.]

Mr. STENHOLM. You may continue, Mr. Goldenberg.

Mr. GOLDENBERG. Thank you, sir.

Just to go back, on civil penalties, in H.R. 4329, a provision to increase civil penalties from \$5,000 to \$25,000 per day for each offense of FIFRA is overburdensome certainly on our industry. And we feel that commercial applicators such as ourselves, as well as farmers, should not—as basic users of these products, should not be included in this category.

The present administrative fine schedule of \$5,000 is more than adequate, plus there ought to be more of a positive and instructional source to help members of our industry correct any violations that may occur. We feel that with the minor-use pesticide situation, which you heard a great deal about today, unfortunately or fortunately, from whichever side of the arena you are sitting, we use minor-use pesticides.

In 1988, when FIFRA was amended, it provided for the reregistration of all products registered prior to 1984. And our concern is that the cost of reregistering these products and registering products for minor use, public health purposes, are of great concern, and that they may not be registered in the future because of the costs.

In 1993, Mr. Dooley and other members of this subcommittee introduced H.R. 1867, Public Health Pesticides Protection Act of 1993, which provides for the continuation of the products necessary for public health pest control, that they be continued to be registered notwithstanding the potential expense. And we would urge that provisions of H.R. 1867 be included in the markup that you plan and you have indicated that you will perform.

I would like to also mention briefly on the necessity to continue as was continued in the previous Congress that issue concerning Federal preemption for those registered, for those using pesticides under FIFRA. Preemption has been picked up by the States, as you are aware, since a Supreme Court decision in 1991. And while many States have enacted preemptions, we support that as well as a Federal role and a Federal preemption partnership program with the States.

It is very important that while we are not concerned with regulation or the difficulty in regulation, we just want to direct it toward us from one source, and that be at the State or Federal level, and not the local communities.

There are several States that still have a patchwork of local regulations that make it very difficult to operate with no benefit to the consumer or the homeowner. We therefore would urge that this committee consider that in its markup.

As always, we from the National Pest Control Association and applicator industry throughout the United States, on behalf of our constituency of customers that rely on us for providing pest control services for the control of the insects which I elaborated earlier, we would urge that and suggest that you continue and your staff continue to use our expertise of our technical folks and others to help you in this very delicate deliberation over this markup.

Thank you very much.

[The prepared statement of Mr. Goldenberg appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.
Next, Mr. Delaney.

STATEMENT OF TOM DELANEY, DIRECTOR, GOVERNMENT AFFAIRS, PROFESSIONAL LAWN CARE ASSOCIATION OF AMERICA

Mr. DELANEY. Thank you.

My name is Tom Delaney, I am director of government affairs for the Professional Lawn Care Association of America, PLCAA, and I appreciate this opportunity to share our views on the Federal Insecticide, Fungicide and Rodenticide Act amendments of 1994, H.R. 4329.

The legislation before us will significantly affect the landscape care industry and the following issues should be addressed and accounted for with any amendments to FIFRA.

Organized in 1979, PLCAA is the only international trade association representing an industry of over 6,000 landscape care companies in the United States and abroad. These companies range in size from small businesses employing as few as one or two people, to large public corporations and franchise operations.

Our industry provides services to residential and commercial customers which include fertilization and pest control, as well as mowing, maintenance, irrigation, aeration, seeding, landscaping, and ornamental and small tree care.

PLCAA promotes professionalism in the industry, develops educational programs, recommends industry standards, and serves as a leading voice in the landscape care industry. PLCAA members are vitally interested in improving many aspects of FIFRA so as to raise environmental consciousness and adhere to existing and new legislative mandates. Some of these issues are not currently addressed in H.R. 4329:

One, certification and training of pesticide applicators. Proper training of employees is one of the most important factors in providing responsible landscape care services to the public. PLCAA plays an important role for its members and others by sponsoring educational seminars, and developing and disseminating training materials for the industry internally and through the media.

PLCAA supports the current certification requirements for pesticide applicators under FIFRA. However, we believe they should be tougher.

Currently, FIFRA allows the application of restricted-use pesticides by technicians who may or may not be trained, so long as the activity is performed under the direct supervision of a certified applicator. A big loophole remains.

The law also permits application of general-use products without any training or without the supervision of a certified applicator. Additionally, FIFRA does not require certification of in-plant workers, such as maintenance personnel. Taken together, these omissions have significant gaps in the current law.

With these concerns in mind, PLCAA recommends across-the-board certification and training requirements for commercial pesticide applicators in H.R. 4329, precisely the same language as was proposed in the Pesticide Improvement Act of 1991, H.R. 3742.

These additions if implemented would raise the standards of our industry by requiring State-approved training for all commercial pesticide applicators regardless of whether the pesticides are classified for general or restricted use.

The need for training and knowledge to properly apply a pesticide should not be limited to restricted-use pesticides, which in fact represent a small amount of the product supplied. While PLCAA believes that the proposed training and certification requirements are essential to responsible landscape care services, our members are concerned that even with this new program, many of the noncommercial users of pesticides, the homeowner or do-it-yourselfer, often applies these products without sufficient information, instruction, or label comprehension.

EPA's 1990 National Home and Garden Pesticide Use Survey suggests that household pesticides are not always used as carefully or effectively as they should. EPA has stated that this survey provides a basis for expanding outreach and education programs on pesticide safety for consumers.

According to the 1991/1992 National Gardening Survey, 62 percent of all households or 58 million households participated in do-it-yourself lawn care in 1991. Only 7 million households employed the services of certified and licensed professional landscape services.

The committee may not be aware that the vast majority of products used by professionals and do-it-yourselfers are the same. Therefore, we recommend that Congress consider adopting a voluntary training program aimed at these nonprofessional users.

By adding these important elements of training, we should be able to address some of the concerns posed in the National Academy of Sciences' report: Pesticides in the Diets of Infants and Children. If nondietary exposures to treated lawns is a concern, why not ensure that all pesticide users be properly educated and trained?

This also relates to my next issue, national regulation of lawn care pesticide applications. PLCAA has led the way in reasonable and responsible regulation of landscape care applications. To that end, our members are prepared to work with Congress and other interested parties to ensure that any legislation ultimately adopted protects both human health and the environment, while at the same time accommodates the practicalities of providing lawn care services.

PLCAA members believe that a nationwide standard will strengthen consumer confidence in the products and services associated with lawn care applications. To go one step further in addressing the National Academy of Sciences concerns, we recommend a standard for nationwide posting of signs when all lawn care applications are made.

Certainly, the use of these signs by all pesticide users will help children avoid possible exposures. PLCAA supports a Federal posting standard for all applications, whether professional or not, with dowels and signs provided by retail establishments for the do-it-yourselfer applicator.

Standardizing these requirements to include homeowners would provide consistent notice to the public of a pesticide application.

PLCAA suggests posting of 5 by 4 inch signs at the primary point or points of entry to the property at the time of actual application.

The required use of these signs in 18 States has proven that the public can easily identify a 4 by 5 sign as a lawn marker and a notice that an application has taken place. The property owner or resident should remove the signs following the application.

The marker notifies the public that an application was made sometime that day and to keep out of the treated area.

Citizen suits. PLCAA opposes the addition of provisions for citizen suits against commercial applicators. The administration has previously stated that problems currently exist with inadequate enforcement of laws, such as Superfund, because too many lawyers and lawsuits bog down the process.

Why invite additional litigation when there is sufficient access in the existing legal process to assist citizens who have claims?

Civil judicial enforcement. PLCAA opposes any provisions that would extend EPA civil penalty authority from \$5,000 to \$25,000 in fines for commercial applicators, farmers, or any other small business entities. Most commercial applicators are not in the same category as large industrial businesses and can ill-afford being fined at the proposed level.

Preemption of local regulation of pesticide use. PLCAA believes that any comprehensive pesticide legislation must provide for a national standard with preemption of local regulations where necessary to allow commercial applicators to continue to conduct business in a responsible manner. PLCAA stands ready to assist the subcommittee in developing protective language toward reasonable and responsible regulation of the landscape care and pesticide user industry.

Thank you, Mr. Chairman, for the opportunity to present these comments and recommendations.

[The prepared statement of Mr. Delaney appears at the conclusion of the hearing.]

Mr. STENHOLM. Dr. Hazeltine.

STATEMENT OF WILLIAM HAZELTINE ON BEHALF OF THE AMERICAN MOSQUITO CONTROL ASSOCIATION

Mr. HAZELTINE. Mr. Chairman and members, my name is William Hazeltine, and I am here making a statement on behalf of the American Mosquito Control Association.

We thank you for the opportunity to present testimony and my comments will be focused primarily on H.R. 4329, as it impacts our ability to provide the best mosquito and vector control. The issues which are of concern to us is the continuing loss and the absence of any new effective pesticides to protect the health of the public we serve.

I reviewed 4329, and while it considers some of our needs, it only considers help with defensive actions in providing some relief from risks of cancellation or suspension. It does not consider the need for a more streamlined and fast registration process for uses of new pesticides for health protection. While we appreciate any help the administration wants to provide, we feel that the proposal that they have made does not provide the mechanism that we need.

H.R. 4329 considers public health pesticide uses specifically in the following places: On page 33 at line 15, on page 48 at line 19, there is provision for consultation with the Secretary of Health and Human Services regarding any proposed suspension or cancellation. Again on page 86, line 1, it provides for consultation with the Secretary of HHS before suspension or cancellation of a pesticide registered for public health or health protection uses, as a way to decide whether the potential benefits for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary of HHS to conduct or arrange for the studies required by the Administrator of EPA, to support continued registration. It then outlines the mechanism for such research and support.

We see some other general problems with the administration's bill. Let me tick these off for you.

We suggest that the well-defined standard for any registration related action using the term "unreasonable adverse effects on the environment," be retained, and that any new standards such as that on page 59 for similar ideas but using different words be avoided.

I can recall in the 1971 legislative turmoils to produce the 1972 amendments, that this issue received an unreasonably large amount of time and I feel that what came out of it, the risk-benefit balancing requirement, was an extremely good and well-thought-out provision. If there is any provision—any problems with implementing this provision, I feel it is the EPA fails to recognize the benefits. They have institutionalized risks, but benefits seem like they are too hard to understand.

The term "minor use" is defined on page 82 and 83. We prefer the simpler yet adequate definition found in the present version of Mr. de la Garza's bill, H.R. 967, or the definition of the Dooley-Herger bill, H.R. 1867. Either one of these is sufficient to establish a workable standard.

The definition of "biological pesticides" on page 68 includes the term, "any organism that is a biological control agent." If this definition is adopted, it would require the registration of all biological control agents, before they can be used in pest control.

In the case of mosquito control, we use mosquito fish extensively, and it would add an unnecessary burden on our operations if we had to have registration, labels, and accepted directions for use on a barrel of fish which we might collect from one pond and take to another.

Additional problems involve the question of who would be the registrant. We seriously doubt the wisdom or necessity of trying to bring living biological control agents under EPA's pesticide registration authority.

If the administration's bill is seriously considered for adoption in its present form, we hope the subcommittee will consider the major problems which we have identified.

The most important amendment we see is the need to add the substantive provisions of H.R. 1867 to the end of section 10 of the administration's bill, or to what other vehicle you intend to use.

We want it to be made perfectly clear that registration of new products is an important aspect of the public health issue in pes-

ticide registration. We would like to see separate risk-benefit balancing for these pesticides.

While our testimony is focused on H.R. 4329, we don't want to exclude any others. We feel that our suggestions for H.R. 1867 could be added to the Lehman-Bliley-Rowland bill. It could be added, perhaps as a joint bill with the de la Garza bill minor use, and ours, and perhaps others, the microbial issues might be added to make a comprehensive minor-use package.

I am also submitting for the record a copy of a paper that I wrote entitled: Mosquitos, Disease and Endangered Species.

Let me point out to you that mosquito vectored virus diseases not only affect humans, but we find they are affecting endangered species. The incidence in California, the farmer that plowed and killed some kangaroo rats. That particular kangaroo rat is also susceptible to mosquito-vectored virus diseases.

And if we are going to go to the extent of arresting or impounding a person's tractor and disk for killing a kangaroo rat or two, it seems to me that we ought to also add with equal vigor some provisions for protecting those kangaroo rats from virus diseases. And I think EPA has a duty under the Endangered Species Act to do everything necessary to provide this.

So it may be if the humans' health doesn't count, maybe we could get this provision justified to protect an endangered species.

Thank you very much for your courtesy in inviting our testimony.

[The prepared statement of Mr. Hazeltine appears at the conclusion of the hearing.]

Mr. STENHOLM. Next, Mr. Karmol.

STATEMENT OF DAVID L. KARMOL, GENERAL COUNSEL, NATIONAL SPA AND POOL INSTITUTE

Mr. KARMOL. Good afternoon, Mr. Chairman and members of the subcommittee.

My name is Dave Karmol, I am general counsel for the National Spa and Pool Institute, and I appreciate the opportunity to appear before you today to discuss our concerns with H.R. 4329 and its impact on the pool and spa industry.

NSPI is the national trade association of the pool and spa industry, with over 4,400 members involved in all segments of the industry, including the manufacture of pools, spas, and related equipment and chemicals; construction and reconstruction of pools, spas, and water features; wholesale and retail distribution of pool and spa products and chemicals; and the servicing of pools and spas.

I have included additional background in my written testimony which I understand will be made a part of the record, but I will not repeat it now.

Suffice to say that NSPI has been involved for years in pool safety, chemical handling, and industry education issues. We believe at the outset it is important to understand what chemicals are used in the sanitizing and disinfecting of pools and spas and whether these chemicals are classified as restricted-use or general-use pesticides under FIFRA. Pool chemicals generally fall into several distinct categories: Balancers or stabilizers to maintain proper pH and alkalinity; mineral additives to maintain proper levels of mineral substances in the water; clarifiers and flocculents, which help col-

lect suspended particulates; and disinfectants and algicides, which destroy bacteria and inhibit pool and spa algae.

Only the latter two types of products, disinfectants and algicides, are pesticides and are regulated as such by the EPA. With the exception of gaseous chlorine, which is delivered in pressurized cylinders, all chemicals used in treating pool and spa water are available both to pool servicing firms and to the general public directly.

No substance now approved for use in the normal servicing of pools is listed as a restricted-use pesticide. FIFRA, as you well know, is sweeping legislation regulating all pesticides to some degree based on their risk to man and the environment.

Some pesticides are banned entirely from production and use, other restricted-use pesticides may be applied only by certified applicators, and many more common pesticides are required to be labeled for proper use and application by consumers.

All forms of chlorine and bromine compounds used for pool disinfection, as well as all algicides and some other pool additives, are classified by the EPA as general-use pesticides under FIFRA. General-use pesticides as defined by Congress in the initial FIFRA legislation, are pesticides which pose little or no risk to man or the environment when used according to label instructions.

General-use pesticides are sold over the counter to the general public and, in fact, most pool chemicals are purchased and applied by pool and spa owners. The application of these chemicals is a simple matter of adding a certain number of pounds or ounces of the chemical for every 10,000 gallons of water in the pool or ounces per 100 gallons in the case of a spa.

The regulatory scheme of FIFRA currently requires States to administer programs to register and certify applicators of restricted-use pesticides, as has been pointed out.

As introduced, H.R. 4329 would change this requirement, by expanding the definition of a commercial applicator to "one who applies any pesticide for hire as a principal part of the business or work of the person." As applied to our industry, this would require that all pool service personnel, summer lifeguards, and community pool operators, many of whom are temporary employees hired for the swimming season, be registered and certified by the State.

Each employee would be required to attend and pass a State-approved comprehensive pesticide training course, including the identification of various rodents, insects, and fungi, and the selection of the proper pest control chemical or technique. Almost none of the training required by most States has any relevance at all to the proper treatment of pool water, which involves maintaining a proper pH level, and a proper level of free chlorine and/or bromine.

Today, many industry employees are graduates of the NSPI institute training program known as Tech I, Tech II or certified. Over 2,000 pool service personnel have earned one of these designations since we began the program in 1989.

In addition, most State health departments impose requirements on pool operators, requiring them to meet specific knowledge standards relating to proper pool water treatment.

We propose an amendment to H.R. 4329. If this section is taken from H.R. 4329, we would hope the committee would consider this as a committee amendment, and would exempt those who apply

general-use pesticides solely for the purpose of cleaning, sanitizing, disinfecting, painting or for use in construction or renovation.

This amendment does not exempt any persons currently regulated under FIFRA. It simply continues a current exemption from the registration and certification requirements, as long as they are using only general-use pesticides in their work.

It would allow the pool and spa industry to continue the employment of some 25,000 individuals in the pool service business under current regulations and requirements. The proposed amendment is attached to our statement.

We have met with the EPA and they indicate that it was not their intention to include pool service in the legislation. We have requested that opinion in writing, and will be happy to share that with the committee when we receive it.

Mr. Chairman, I want to thank you and the other members of the committee for your patience and endurance today and we look forward to working with you and your staff as this process goes forward.

Thank you.

[The prepared statement of Mr. Karmol appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Mr. Smith.

Mr. SMITH of Oregon. No questions.

Mr. STENHOLM. Mr. Pomeroy.

Mr. POMEROY. Mr. Chairman, I want to thank you for running a 7-hour hearing so I got to attend part of it. I have had—

Mr. STENHOLM. We don't want to make it any longer than necessary, Mr. Pomeroy.

Mr. POMEROY. I have had a busy day and deeply regret missing this important day, because I am worried—as we address the very critical social policy ends that are the object of this legislation—that we don't have a proliferation of unintended consequences that make perfectly legitimate industry practices inadvertently illegal and impermissible.

I think a hearing like you have had today and the testimony which I and my office will be evaluating very carefully, will provide us with a much better feel for that.

Thank you.

Mr. STENHOLM. I don't have any questions.

Any of you have any additional comments of anything that you might wish to add to the record at this point?

It is a rather remarkable coalition of support for a bill and for ideas that we have heard from today. I think there are many good suggestions that have been made.

Again, the base bill with those improvements that the administration has suggested, of which there is concurrence that it moves us in the right direction, and perhaps after today's hearing we will find some additional changes that will encompass the spirit of what is needed by all of the witnesses today, and that we can in fact move forward.

When you have more than 218 cosponsors of a bill, that is usually evidence of fairly significant broad support. It does not necessarily guarantee that when it gets to the floor you will have 218

votes, as we have learned the hard way in the past, but it does give ample reason, as I have been asked by some of the press: Do you really expect to get a bill this year?

As far as we are concerned, we do. The administration wants a bill and we can proceed forward, and I think they do, I think that it is very possible. And that is the spirit in which we intend to move forward.

There are so many areas and so many areas in which the so-called "minor use," the so-called "specialty products," of which common sense tells us that there ought to be, "exemptions," et cetera, I would encourage each of you not to seek out your own special exemption but stay a part of the coalition. Because the important thing is that if we pursue legislation that we eventually get a Presidential signature. Otherwise, it doesn't do us any good. And, therefore, I encourage everyone to stay within the coalition that you put together, testify in the same spirit—not testify, proceed in the same spirit that you testified today.

We thank you for your input, we thank you, too, for your patience. We appreciate the fact, that in accommodating the administration, we have made some problems for some of the rest of you that would have been through a little bit earlier had we not had the change as we did. But I think in all fairness, and with the scheduling problems of the Congress in general, that warts and all, it has worked out fairly decent today.

We appreciate your patience, your testimony, look forward to working with you.

Nothing further to come before this subcommittee, we will stand adjourned.

[Whereupon, at 3:50 p.m., the subcommittee was adjourned, to reconvene subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

TESTIMONY OF
 LYNN R. GOLDMAN, M.D.
 ASSISTANT ADMINISTRATOR
 FOR PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
 U.S. ENVIRONMENTAL PROTECTION AGENCY
 AND
 JAMES R. LYONS
 ASSISTANT SECRETARY
 NATURAL RESOURCES AND ENVIRONMENT
 U.S. DEPARTMENT OF AGRICULTURE
 AND
 MICHAEL R. TAYLOR
 DEPUTY COMMISSIONER
 FOR POLICY
 U.S. FOOD AND DRUG ADMINISTRATION
 BEFORE
 SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
 COMMITTEE ON AGRICULTURE
 U.S. HOUSE OF REPRESENTATIVES

JUNE 15, 1994

I. INTRODUCTION

Good morning, Chairman Stenholm and Subcommittee members. We are pleased to appear before you today to discuss the major pesticide/food safety legislation pending before your Subcommittee. We appreciate your initiative in scheduling these hearings and your continued interest and forbearance in working with us to complete the important task of legislative reform in this Congress.

As you know, the Administration has submitted legislative language to implement the proposals presented before your subcommittee last fall. These proposals were introduced last month into the House of Representatives and the Senate as the Pesticide Reform Act of 1994 [H.R. 4362 and S. 2084, amending the Federal Food, Drug, and Cosmetic Act (FFDCA)] and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Amendments of 1994 (H.R. 4329, S. 2050).

Taken together, the Administration's bills provide a comprehensive set of reforms to the nation's pesticide statutes and a

- 2 -

resolution to the problems and controversies associated with pesticide regulation.

Today, we want to review the goals of our legislation stated last fall by Administrator Browner, Commissioner Kessler and Deputy Secretary Rominger. As we will explain, those goals are no less important, and the need for legislation no less urgent, than they were last fall. In fact, we think that the leadership you have shown in organizing this hearing and the willingness of other witnesses to express their views today is a signal that the this issue can and should be resolved. The Administration's approach offers the most comprehensive proposal available for crafting that resolution.

II. GOALS OF LEGISLATIVE REFORM

The Administration's bills represent a collaborative effort of the Environmental Protection Agency (EPA), U.S. Department of Agriculture (USDA), and the Department of Health and Human Services and its Food and Drug Administration (HHS/FDA). The goals of that effort were to resolve the conflicts in current law with a health-based standard for pesticides in food which also provided full protection for the diets of infants and children, to ensure that the regulatory system acted in a timely and appropriate manner to eliminate unacceptable risks, and to make certain that the producers have sufficient safe and efficacious materials to raise their crops in a way that contributes to profitability and sustainability.

Our bills will improve existing legislative authorities governing pesticides in many areas. They directly address the recommendations put forth in the National Academy of Sciences (NAS) report, "Pesticides in the Diets of Infants and Children." Our FIFRA

- 3 -

amendments also address specific needs for reform that were identified by the Administrative Conference of the United States (ACUS) that go to the heart of the credibility gap between consumers and government when it comes to pesticides. These reforms will help reorient our efforts to focus on preventing problems at the source, through appropriate reduction of pesticide risks. History teaches us that in all aspects of life, prevention saves time, energy, and resources. By stressing prevention, we will be protecting health and the environment not only for ourselves and today's children, but also for future generations.

III. NEED FOR LEGISLATION

The approaches we advocate would change how pesticides are used and regulated in this country, and offer the promise of far-reaching public health and environmental benefits. They will complement our ongoing administrative initiatives, encourage the development and use of safer alternatives, respond to the recommendations of the NAS report on how to ensure that children are protected from potential pesticide risks, and streamline regulatory programs to improve our ability to act promptly and effectively.

In addition, as you well know, court decisions have mandated strict implementation of the provisions of the Delaney Clause in Section 409 of the FFDCA.

Table 1 shows pesticides, crops and states potentially affected by the U.S. Court of Appeals for the Ninth Circuit's decision in Les v. EPA. We are moving forward to implement the court mandate. By an order signed this week, EPA finalized the revocations of the food additive regulations for the pesticides remaining from the Delaney litigation. The next step, proposing revocation of current Section

- 4 -

409 tolerances involving a number of pesticides and crops not part of the original lawsuit, has been prepared by EPA, and publication is expected soon.

A simple "Delaney fix" is not enough. Only a rational system to set tolerances will protect public health and ensure public confidence in the food supply. We need to address the ACUS recommendations to instill credibility in our regulatory programs. That is why our bills would amend both FIFRA and the FFDCA. Only by reforming both statutes can we achieve the important public goals of food safety, health and environmental protection and establish a consistent framework for timely regulatory decision-making. Change is long overdue.

IV. PENDING LEGISLATION

Three major bills to amend the laws governing pesticides and food safety regulation are now pending in the House of Representatives: the Administration's pesticide and food safety reform legislation (H.R. 4329 and H.R. 4362); the Pesticide Food Safety Act (H.R. 4091) introduced by Representative Waxman; and the Food Quality Protection Act (H.R. 1627) sponsored by Representatives Lehman, Bliley, Rowland and others.

All three bills address some of the same issues, but there are significant differences among them. The balance of our testimony today will focus on the major points of the two bills before your Subcommittee. H.R. 1627 contains both FIFRA and FFDCA amendments and has similarities to the Administration's approach. However, there are also significant differences between the bills. Tables 2 and 3 contain summary comparisons of these proposals.

Although only the FIFRA provision of the Administration's bills and H.R. 1627 are directly in the jurisdiction of this Subcommittee,

- 5 -

the FFDCA amendments are just as essential to a full reform of the nation's pesticide laws. For that reason, we will discuss key provisions of the FFDCA amendments in addition to the FIFRA provisions. Of course we will continue to work directly with the Energy and Commerce Committee and Mr. Waxman's Subcommittee on the FFDCA legislation.

A) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
Proposals

FIFRA governs the registration and reregistration of pesticides by EPA and contains a number of other pesticide regulatory authorities not directly tied to residues in food. FIFRA amendments relating to eleven major issues are found in the Administration's bill H.R. 1627, or both.

1) Registration "Sunset"

Under the Administration proposals, pesticide registrations would be required to be reviewed and renewed on an active ingredient basis every 15 years, to ensure they are in conformity with current scientific standards. Complete applications must be submitted to EPA by year 12 after initial registration or registration renewal. For the initial implementation of the 15-year cycle, the legislation would allow for grouping pesticides in a way that permits EPA to balance workloads and avoid skewed distributions in the numbers of pesticides that "come due" in any given year.

H.R. 1627 contains no comparable provisions.

Scientifically-based regulation of pesticides need to respond to changes in science and our understanding of pesticides and their effects. A sound regulatory system requires an orderly process for incorporating evolving science and a process to ensure that the

- 6 -

enormous backlog in evaluation encountered initially in reregistration will not occur in the future.

2) Phase-Out/Phase-Down

The Administration proposals provide that, whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could by rule-making take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing production caps or placing restrictions on specific uses. EPA would consult with USDA in establishing phase-out requirements to avoid unnecessary dislocations.

H.R. 1627 contains no comparable provisions.

By providing an intermediate process to reduce potential risks while scientific questions are answered, this provision offers an alternative to lengthy special reviews. In doing so, the public can be assured that timely action is being taken while ensuring that an orderly process exists for maintaining important uses. The Administration's provisions are consistent with ACUS recommendations for providing EPA with phase-down authority and creating incentives for sound data development.

3) Streamlining Label Changes And Establishing Uniform Label Compliance Dates (Label Call-in Authority)

The Administration's proposals include a new provision, modeled on the existing "data call-in" authority of FIFRA Section 3(c)(2)(B); to establish a streamlined process for achieving relatively small changes in the conditions of registration (e.g. label changes that reduce pesticide risks but do not affect the availability of a pesticide for use on any particular site). An annual uniform labeling

- 7 -

effective date would be established, and registrants would be able to make label changes in a predictable, orderly fashion.

H.R. 1627 contains no comparable provisions.

The label call-in process establishes a means for making label changes in a unified way without relying on cancellation to enforce compliance as under current law. The changes proposed by the Administration would correct problems identified by the chemical industry by leveling the playing field for registrants and simplifying the compliance process.

4) Incentives For Development Of Reduced Risk Pesticides

The Administration's proposals would require EPA to establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria would qualify for priority review, and, if approved, would be accorded two additional years of exclusive data use, beyond the ten years now provided.

EPA could also grant special conditional registrations for biological pesticides posing low potential risks. In addition, deadlines would be established for EPA to act in approving new alternatives that would lead to a more timely and appropriate review process and improve the market potential for new materials.

H.R. 1627 contains no specific comparable provisions.

While the prevention of unreasonable adverse effects from pesticides is important, the needs of agriculture for sound pest management tools are just as significant and pressing. It is incumbent upon the regulatory system to not only deal with pesticide risks in a timely fashion, but also to ensure that new materials are available to producers in just as timely a fashion. Full reform of pesticide laws must take particular care to make the necessary tools

- 8 -

available for the production of an abundant and affordable food supply.

5) Alternatives, Integrated Pest Management (IPM), and
Pesticide Risk And Use Reduction

Consistent with the NAS Report, "Soil and Water Quality: An Agenda for Agriculture," the Administration proposal embodies clear policy goals favoring safe and efficient use of pesticides. Our proposal includes provisions that direct federal agencies to take a leadership role in technology development and transfer and implementation of Integrated Pest Management, as well as authorizing USDA to set national implementation goals for its research and education programs. In addition, the current prohibition on requiring IPM training as part of certification and training programs would be repealed. The statute would also authorize regional ecosystem-based pilot projects designed to reduce aggregate pesticide risks. and provide a mechanism to focus research priorities.

EPA and USDA would be required to work together to develop and make available comparative information on the environmental and health effects of pesticides and to identify the research, education and extension activities that are most promising in terms of meeting pest management needs and reducing risk concerns associated with the use of pesticides.

The statute would require EPA to identify pesticides of regulatory concern in conjunction with USDA's assessments of situations in which there are limited alternatives. USDA would then use this information to focus its research and education efforts to ensure that alternatives were developed that provide producers with adequate alternatives that also mitigated the risk concerns.

- 9 -

EPA would be authorized to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and pesticide resistance management programs.

H.R. 1627 provisions are less extensive. EPA and USDA are directed to research, develop and disseminate IPM techniques and other methods of pest control that enable growers to reduce or eliminate applications of pesticides that pose greater than negligible dietary risks. Fruits and vegetables critical to a balanced, healthy diet -- so called "minor crops" because of their acreage -- are emphasized.

As in the provisions for reduced risk pesticides, these Administration amendments provide directly for the expanded development and use of proven pest management systems, such as IPM, and a coordination of federal efforts to provide producers with critically needed alternatives. Both areas must be addressed comprehensively if serious reform is to be achieved.

6) Improved Pesticide Data Collection/Record-Keeping

Following the model of the 1990 Farm Bill provisions, which applied only to restricted use pesticides, the Administration's legislative proposals would require record-keeping for all agricultural pesticide use.

H.R. 1627, does not include new record-keeping requirements, although USDA is required to coordinate with EPA in collecting pesticide use data through surveys and to make survey results available for pesticide exposure assessments and benefits analyses.

Given the need for reliable data to assess actual exposure, the Administration's proposal would ensure that the data collected provide a sound basis for realistic decision-making.

- 10 -

7) Pesticide Minor Uses

Incentives for registering minor uses under the Administration's proposals include priority review and extended exclusive data use rights. In reregistration under amendments to FIFRA enacted in 1988, unsupported minor uses lacking only residue chemistry data could continue until the last study for the pesticide is due, and registrants would have until that date to supply data for the minor use.

EPA, and the Department of Health and Human Services/Public Health Service (HHS/PHS) would collaborate to identify critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

There are no minor use provisions in H.R. 1627. We recognize that other legislation has been introduced that does deal with minor use issues, including H.R. 967, the minor use bill sponsored by Agriculture Committee Chairman de la Garza and others, and Representative Dooley's bill, H.R. 1867, on public health pesticides.

The problems facing producers who rely on minor use pesticides have been widely discussed and documented. In pursuing comprehensive reform, the Administration proposal, strengthens incentives for registrations of minor use pesticides and eliminates regulatory obstacles that have impeded the availability of materials critical to producers. We are anxious to work with you and other members of the Agriculture Committee to ensure these matters are fully addressed in a comprehensive reform measure.

- 11 -

8) Cancellation And Suspension Procedures

Consistent with the ACUS recommendations, we believe the cancellation process needs reform to enable more timely action and enhance regulatory credibility. Under the Administration's proposals, cancellation procedures would be amended to replace formal, trial-type proceedings before an Administrative Law Judge (ALJ) with a notice-and-comment cancellation process. Suspensions would be decoupled from cancellation procedures, and the time-consuming and cumbersome ALJ process for challenging suspensions would be replaced by a petition procedure and prompt judicial review.

These procedural approaches are generally consistent with the findings of the ACUS, which basically called for eliminating formal adjudicatory hearings and replacing current procedures with an informal notice and comment process, including notice to registrants and others through publication in the Federal Register and a reasonable opportunity for written comments.

H.R. 1627 would replace current FIFRA cancellation procedures with a process described as "informal rulemaking," but add steps not required under existing law or by the Administration's proposals.

We are concerned that the net effect of H.R. 1627's provisions would be to increase the time required to take action against pesticides found to pose unreasonable risks, and even to make relatively minor changes that will reduce risks and improve proper pesticide use. By contrast, the Administration is proposing a simplified, straightforward cancellation procedure that protects procedural rights and is consistent with the notice-and-comment process followed for most regulatory rulemaking actions in this country. Table 5 compares the major features of the two bills.

- 12 -

Specifically, our proposal requires:

- o CONSULTATION AND OPPORTUNITY FOR COMMENT BY OTHER FEDERAL AGENCIES AND THE SCIENTIFIC ADVISORY PANEL (SAP)

Under the Administration proposal, there would be prior consultation and opportunity for written comment on proposed cancellation actions by the Secretary of Agriculture (agricultural pesticides) or Secretary of Health and Human Services (public health pesticide uses). The SAP would also be notified and given an opportunity to submit comments on the health and environmental impact of the proposed order.

- o ISSUANCE OF PROPOSED ORDER FOR PUBLIC COMMENT AND NOTICE OF OPPORTUNITY FOR A HEARING

The proposal must be published in the Federal Register and a copy provided to each registrant of the affected pesticide.

There would be at least 90 days for comment, and the proposal must include information on the factual and legal basis of the proposed cancellation, an analysis of effects on agriculture and consumers in the case of agricultural pesticides, and copies of any comments received from USDA, HHS, or the SAP. The proposed order would also include notice of the availability of an informal public hearing.

- o INFORMAL PUBLIC HEARING OR NOTICE OF HEARING REQUEST DENIAL

If requested, within 21 days of publication of the proposed order, the Administrator must either schedule a public hearing or, if the Administrator determines

- 13 -

that a hearing is not in the public interest, publish a notice of the denial and the reasons for the denial in the Federal Register.

o FINAL ORDER

If, after reviewing the comments and hearing record, the Administrator determines that the cancellation standard is met, EPA shall publish a final order in the Federal Register containing the factual and legal bases of the final determination, summary of significant comments received and responses to them, and, where applicable, an analysis of the impact on consumers, food prices, and the agricultural economy. Copies must be provided to all affected registrants.

If the Administrator determines not to cancel, a final decision to that effect must be published and provided to each affected registrant.

All final orders would be subject to judicial review under FIFRA, unless no comments opposing the proposal are submitted during the comment period or at any hearing.

In addition, an applicant for registration may provide new information that may lead to reconsideration of a final order. Such reconsideration would require publication in the Federal Register and at least 60 days for public comment on whether the request for reconsideration should be granted and the registration approved. Decisions on reconsideration are judicially reviewable.

The cancellation procedures prescribed by H.R. 1627 contain additional, time-consuming steps. Also, in the absence of "label

- 14 -

call-in" or other provisions, the effect of H.R. 1627 appears to be to require this full procedure for all changes in labeling, packaging, composition, or classification of a pesticide. (The Administration's proposals allow relatively minor changes that do not affect the availability of a pesticide for a use site to be made using a streamlined procedure.) The steps required by H.R. 1627 include:

- o FORMAL REVIEW OF EVIDENCE BY INTERNAL COMMITTEE
An expert committee of EPA employees or consultants who have not been involved in any previous analysis must provide written recommendations on whether the standard for initiating proceedings is met.
- o PRIOR NOTICE TO PESTICIDE REGISTRANTS AND FEDERAL AGENCIES
Registrants would have 30 days to respond to this pre-notice. The Secretary of Agriculture would have to prepare an analysis of benefits and use data when an agricultural commodity would be affected.
- o ADVANCE NOTICE OF PROPOSED RULEMAKING (ANPRM)
After receiving the recommendations of the review committee and any comments submitted by registrants, USDA and HHS, EPA would publish an Advance Notice of Proposed Rulemaking, or a notice of a proposed decision not to initiate rulemaking, and allow at least 60 days for comment.
- o NOTICE OF PROPOSED RULEMAKING (NPRM)
This notice must include detailed information, including the major scientific assumptions, legal interpretations, and policy considerations underlying the proposed rule and a summary of available risk-benefit information. At least 90 days would be provided for comment, and each commenter must

- 15 -

submit a report on all scientific data on risks and benefits in the commenter's possession, unless those data were in the bibliography published with the proposal. USDA and HHS will be provided copies, and USDA must prepare an analysis of the potential impact of the proposal on the domestic and global availability and prices of agricultural commodities, retail food prices, and societal impacts including consumer nutrition and health of low-income consumers.

o HEARING

If requested by any commenter within 15 days of the close of the comment period on the proposal, a hearing is to be scheduled within 60 days of the close of the comment period. It is not to exceed 20 days in duration.

o SAP REVIEW, HEARING AND REPORT

EPA would provide a copy of the proposal to the SAP at the time of publication and, if any comments are received opposing the proposed rule, request SAP recommendations on the health and environmental impact of the proposal and any significant issues of fact or science policy. The SAP may hold a public hearing and is to report to EPA within 30 days of the close of the comment period on the proposal or within 30 days of any hearing on the proposal. EPA must allow a "reasonable time" for written public comment on the SAP report.

o FINAL ACTION

After consideration of all the material in the rulemaking docket, EPA shall publish either a final rule or withdrawal of the proposed rule, accompanied by a statement

- 16 -

responding to the comments received, explaining reasons for differences from the proposal, and describing the impact on food prices and the agricultural economy.

After the procedures in H.R. 1627, final actions would be subject to judicial review, as would final orders under the Administration's proposals.

A general consensus has emerged among a wide array of interests that cancellation and suspension proceedings can and should be streamlined and that courts of law are hardly the best place to decide scientific issues. Without altering the standards for action, the Administration proposal establishes an orderly mechanism that provides public credibility for regulatory action while preserving essential due process considerations.

9) Enforcement Authorities

FIFRA enforcement provisions are significantly limited, even though violations may result in serious harm to health or the environment. The Administration is proposing to modernize FIFRA by including improved inspection, record keeping and lab audit authorities and "whistle blower" and citizen suit provisions. The Administration proposal will increase the flexibility of FIFRA enforcement, allowing the federal government to seek civil penalties from the courts, in addition to criminal sanctions. Potential civil and criminal penalties for FIFRA violations would be significantly increased, providing EPA and the courts with the flexibility needed to impose penalties commensurate with the nature of the offense. The Administration's proposal will also provide the federal government with the authority to take immediate action, as may be necessary in

- 17 -

emergency situations. All regulations under FIFRA would be fully enforceable.

H.R. 1627 has no comparable provisions.

10) Pesticide Export Restrictions

Generally, the Administration's legislation would prohibit the export of pesticides not approved for use in the U.S., with certain limited exceptions.

Export of any pesticide to a country that has decided that it does not want to receive shipments would be prohibited, as would export of any pesticide that has been denied registration or administratively or voluntarily canceled for all or virtually all uses in the U.S. based on health concerns. Voluntarily canceled or withdrawn pesticides could be exported if the Administrator determines that there is no information indicating their use could pose significant health or environmental concerns that would require restriction. Other pesticides which do not raise health concerns (e.g., pesticides that may have been canceled due to environmental risks) could be exported to countries that specifically request them and only if the Administrator makes a finding that they have not been banned for any reason related to an adverse health effect.

Never-registered pesticides could be exported if there were a U.S. tolerance in place, or if they had been approved in at least three countries that have sound regulatory systems and require independent review of scientific data as a condition of pesticide marketing. Analytical methods would also be required for all food use pesticides.

Export-related activities by EPA would include enhanced technical cooperation with developing countries to improve pesticide use and

- 18 -

regulation. Additional provisions would require pesticide manufacturers to accept responsibility for sound product stewardship throughout the world, improve information on exports and make it publicly available, and otherwise enhance EPA's programs under Section 17 of FIFRA.

H.R. 1627 has no comparable provisions.

The debate over the export of pesticides has raised concerns over the food supply and has posed problems for registrants in making investment decisions. The Administration bill offers a resolution that relies on the informed decisions of foreign countries in the exportation of pesticides while preventing situations that would jeopardize public health abroad.

11) Fees To Support FIFRA '88 Reregistration

To address a shortfall in funds to support ongoing reregistration activities under FIFRA '88, our proposals include authority to impose a new one-time supplemental reregistration fee assessed on an active ingredient basis and an individual product reregistration fee. Annual maintenance fees as required under the current reregistration program would continue.

Failure to provide the resources we seek through these fee proposals could have significant repercussions on reregistration schedules and lead to significant staff cutbacks in the pesticide program. EPA would simply not have the resources to carry out its Congressionally mandated responsibilities in a timely fashion.

Tables 6 and 7 illustrate our current projections of the impact on reregistration. Both these tables assume lower rates of rejection of studies submitted to support reregistration as a result of our efforts to work with registrants to identify and eliminate the major

- 19 -

reasons for study failure and improve data quality. If rejection rates remain at historical levels, further delays are likely.

H.R. 1627 has no provisions to meet these resource needs and keep reregistration on track.

B) Federal Food, Drug, And Cosmetic Act (FFDCA) Proposals

Under the FFDCA, EPA sets tolerances, or maximum legally permissible levels, for pesticide residues in food. The FFDCA is also the source of FDA authority to monitor the food supply and enforce the tolerances set by EPA.

1) Standards For Tolerance-Setting

Under the Administration's proposals, tolerances for pesticide residues in all types of food would be based on a single, health-based standard, defined as "a reasonable certainty of no harm" to consumers of the food. For carcinogens, this is the negligible risk standard. The new uniform safety standard would replace the current conflicting standards in Sections 408 and 409 of FFDCA and would be the basis for regulating pesticide residues in all types of foods, whether raw or processed, for all health risks, cancer and non-cancer.

The statute would specify factors EPA should consider in assessing pesticide risks as part of the tolerance setting process, including, for example, risks to significant subpopulations, risks from multiple sources of exposure in addition to food, and risks from pesticides that have a common mechanism of action. EPA would also have clear authority to set multiple tolerances for residues in foods at different points in the food production and distribution chain, including at the farm gate and at the point of retail sale, thereby allowing for the use of lower anticipated residues in exposure assessments. Dietary exposure estimates would apply the protective

- 20 -

assumption that residues are present in foods at the applicable tolerance levels, but would explicitly permit exposure assumptions to be adjusted to reflect the percentage of a crop actually treated with the pesticide, when reliable data are available.

H.R. 1627 would amend FFDCA to establish a negligible risk standard for tolerances for pesticide residues in raw and processed foods, but does not define what assumptions should be made to protect public health. H.R. 1627 would direct EPA to take various factors and "reasonable assumptions" into account in tolerance-setting, which are to be defined by regulation. If reliable data are available, the EPA would be required to base its exposure assessments on actual residues rather than assume residues are present at tolerance levels. Percent of crop treated data would also be used in calculating exposure.

Perhaps most significantly, H.R. 1627 would allow risks that exceed negligible to continue indefinitely, if outweighed by the benefits of the pesticide. Economic considerations could over-ride concerns about dietary risk. Conceptually, this represents a key difference in approach.

The Administration bill would establish a strictly health-based standard for food safety, while providing for a transitional period during which benefits could be considered in circumstances involving significant benefits to consumers or impacts on domestic food production. Our experience to date leads us to believe that excluding consumer and producer benefits from consideration will not cause major problems. Therefore, the statutory changes we advocate are not likely to cause significant disruption, especially given the ten year transition period we have provided for those situations in which

- 21 -

significant direct consumer benefits might be lost, or which could lead to significant disruption in domestic food production.

A single, health-based standard for food safety is critical to guiding decision-makers, as well as for assuring American consumers that the pesticides used in food production will not pose risks to their health. A legislative proposal that does not do everything possible to ensure public confidence in the safety of the food supply, now in and in the future, will not serve the interests of agricultural producers or consumers.

2) Special Provisions For Infants And Children

The Administration's proposals for establishing tolerance levels contain additional requirements that are directly responsive to the recommendations contained in the 1993 National Academy of Sciences report, *Pesticides in the Diets of Infants and Children*. Specifically, EPA would be required to consider unique consumption patterns in children's diets and special susceptibilities to pesticide risks. EPA would publish specific findings that tolerances are safe for infants and children. (Table 4)

EPA would evaluate multiple exposures when establishing tolerances and, when appropriate, apply an additional safety factor and/or take other necessary steps to ensure safety for infants and children.

The Administration bill also would require the Department of Health and Human Services and USDA, in consultation with EPA, to conduct surveys to determine dietary exposure to pesticides among infants and children. We believe that such information is critical to ensure that the exposure estimates EPA uses in its risk assessments are protective of children, in keeping with the NAS report.

- 22 -

H.R. 1627 does not directly address children's diets and potential susceptibilities.

A straightforward permanent, specific statutory focus on infants and children is important. The health of our children and the safety of their diets is of paramount concern to all of us. Sound pesticide reform requires particular attention to ensure that our laws are sufficiently protective.

3) Review Of Existing Tolerances

Under the Administration's proposals, EPA would be required to review all existing tolerances and ensure that they meet the new health-based standard within seven years of enactment. Special fast track provisions would require priority review of pesticides which, based on currently available data, appear not to meet the safety standard. EPA would have to identify these pesticides within 180 days of enactment. The review of 75% of such tolerances will be complete within three years, and the review of all these tolerances will be completed no later than four years after enactment. Pesticides subsequently identified as potentially not meeting the standard may be added to the fast track; similar time frames would apply for data submission and review.

H.R. 1627 contains no similar requirements for a review of all existing tolerances.

The review of tolerance provisions would assure that tolerances for older chemicals will be evaluated by a specific deadline. This action would remove the cloud of uncertainty that has plagued these older uses and simultaneously improve the credibility of the federal government's statements as to the safety of the food supply.

4) Section 18 Tolerances

- 23 -

Section 18 of FIFRA allows EPA to exempt a state or federal agency from the requirements of FIFRA if emergency conditions exist which necessitate the use of an unregistered pesticide. Exemptions are most often granted to States for a limited time to allow the application of a pesticide for the unregistered use. Under current law, residues on treated commodities resulting from these authorized uses are not covered by any tolerances or tolerance exemptions. In these situations, it has been customary for FDA to use its enforcement discretion by following EPA-recommended administrative levels and not taking action against products containing the residues resulting from a Section 18 use. FDA does have strong reservations about regularly exercising its enforcement discretion to address these frequently occurring residues.

The Administration bill addresses this situation. H.R. 4362 would require EPA to set tolerances for pesticides for which an emergency use is authorized under Section 18 of FIFRA. Establishment of a tolerance in these instances will not only ensure that the emergency use is consistent with the statutory safety standard for pesticide residues in food, but also would provide FDA with an enforceable limit for residues resulting from Section 18 uses.

H.R. 1627 does not contain a parallel provision.

5) Enforcement Authorities

The Administration bill would provide FDA with three additional enforcement authorities related to foods that contain illegal pesticide residues: embargo, recall, and civil money penalties.

Embargo

H.R. 4362 would give FDA authority to embargo food shipments suspected of being adulterated with an illegal pesticide residue for a

- 24 -

reasonable period until FDA can substantiate whether a violation exists, and if so, to initiate enforcement action against the shipment being held.

Although FDA can request the assistance of the States in stopping the sale or movement of food shipments while FDA develops the documentation for a seizure action, the process can be cumbersome. Indeed, FDA cannot always rely on the State's authority.

Providing FDA with its own embargo authority will allow expeditious action against a food shipment suspected of being adulterated in those instances where a State cannot, or may choose not to, act.

Recall

At the current time, FDA is virtually powerless to track violative food shipments once they have been distributed. The Agency can neither compel the manufacturer or distributor to disclose records that show where the product went, nor to recall the product.

Providing FDA with the authority to compel a manufacturer to recall a food containing illegal pesticide residues would allow for prompt removal of violative goods from commercial channels and better protection for consumers.

Civil Money Penalties

In the past, FDA has not taken action against a person who causes a violative residue in food because criminal prosecution--the only available punishment--has been considered too severe. FDA seizure actions do not provide a direct or particularly effective mechanism for deterrence. Providing FDA with the authority to levy civil money penalties against individuals who cause a food to become adulterated

- 25 -

with illegal pesticide residues or introduce such adulterated foods into interstate commerce would address this situation.

H.R. 1627 does not contain any enforcement enhancements for FDA.

The Administration believes that the pesticide statutes need to be reformed and that providing FDA with proper enforcement tools is a critical and essential part of that reform. We believe that it makes no sense to reform the law if, because of a lack of adequate enforcement mechanisms, it cannot be properly enforced.

6) Residue Monitoring

The Administration bill, H.R. 4362, specifies the following priorities for FDA's monitoring program: testing for pesticide residues determined by EPA to be of special health concern; sampling foods that are high consumption items for infants and children; looking for residues most likely to result in violations; conducting incidence and level monitoring; and conducting a total diet study of pesticide residues in foods as they are consumed.

Although the direction provided by the Administration bill does not differ significantly from what FDA is doing currently under its tolerance-enforcement responsibilities, enactment of the Administration bill would provide a clear statutory mandate that these monitoring activities should continue.

H.R. 1627 does not contain any parallel provisions regarding FDA's monitoring programs.

7) Analytical Methods

H.R. 4362 would prohibit EPA from establishing a tolerance unless an analytical method exists that is capable of detecting and measuring the levels of a pesticide residue in or on the food; with certain exceptions, the method should be a multiresidue method. Requiring

- 26 -

better and more practical analytical methodology, supplied in large part by registrants, for tolerance enforcement purposes should improve FDA's monitoring capability and programs.

In addition, a registrant of a pesticide would be required to provide a sample, or "reference standard," of the pesticide chemical to EPA for eventual use by any laboratory in residue monitoring programs. We believe this provision will help to improve the current system.

H.R. 1627 would permit a petitioner for a tolerance to provide as an alternative to describing a practical method for detecting and measuring the pesticide chemical residue in the food, to provide an explanation as to why such a method is unnecessary. We believe that a practical analytical method must be a prerequisite for registration of each pesticide chemicals for which a tolerance is requested because without such a method, the tolerance is unenforceable.

8) Preemption Of State Tolerance-Setting Authority

The Administration proposals do not address limitations on state authority to set more stringent requirements for pesticide residues in food. Under H.R. 1627, states and localities would generally be prohibited from establishing their own tolerances for pesticides first registered or reregistered after April 25, 1985, or for which there are other "qualifying federal determinations" that protect public health. States could petition for waivers based on compelling local conditions, if the waiver would not unduly burden commerce.

V. CONCLUSION

The many interested stakeholders in pesticide and food safety legislation have differing perspectives on how best to address these complex issues. These stakeholders have proposed competing reform

- 27 -

bills, which have been on the table for several years now. It is critical that we work to move beyond this adversarial debate and seek to identify practical approaches that serve the legitimate interests of all concerned. This has been the Administration's goal in developing its proposals, as we testified last fall.

If we fail in this regard, we will lose a major opportunity to advance public health and environmental protection goals and to maintain and enhance public confidence in food safety and the pesticide regulatory system. We will also miss an opportunity to ensure that the regulatory process explicitly addresses the problems of producers who need effective and safe pest management tools to raise their crops.

We applaud your initiative in conducting these hearings and look forward to working with this Subcommittee and others in Congress to enact meaningful reforms as expeditiously as possible. Changes are long overdue.

(Attachments follow:)

POTENTIAL IMPACT OF THE DELANEY CLAUSE - CROPS, PESTICIDES, AND STATES AFFECTED

Use Site	Pesticides	States Affected
Alfalfa	Hexazinone	
Apples	Benomyl, Captan, Dicofol, Dimethoate, Mancozeb, Maneb, Metiram, Oxyfluorfen, PCNB, Propargite, Thiophanate-methyl, Triadimefon	NY, MI, GA, MD, SC, VA, CT, DE, NJ, PA, New England, Corn Belt, NC, WA, WV
Barley	Mancozeb, Triadimefon	CO, MT, UT, WY, KS, ND, NE, OK, SD
Citrus (Oranges, Grapefruit, Lemons, Limes, Tangerine, Tangelos, Temples)	Benomyl, Dicofof, Dimethoate, Methidathion, Norflurazon, Phosmet, Propargite	FL, CA, AZ
Cotton	Acephate, Dimethipin, Oxyfluorfen, Phosmet	Delta, AZ, NM, NV
Feed items	Tetrachlorvinphos	All U.S.
Figs	Propargite	
Food Handling Establishments	Acephate, Dichlorvos (DDVP)	All U.S.
Grapes	Benomyl, Captan, Dicofof, Mancozeb, Maneb, Norflurazon, Propargite, Tridimefon	CA, NY, CT, DE, NJ, PA, MI
Mint (peppermint, spearmint)	Oxyfluorfen, Trifluralin	WA, OR
Oats & Rye	Mancozeb	

Use Site	Pesticides	States Affected
Packaged, nonperishable food	Dichlorvos (DDVP)	
Peanuts	Alachlor, Metolachlor	GA, MD, SC, VA, NC, Delta
Pineapple	Hexazinone, Triadimefon	HI
Plums & Prunes	Captan, Dicofof, Propargite, Propylene oxide	
Potable water	Simazine	
Potatoes	Chlorothalonil, Linuron, Oxyfluorfen, PCNB, Trifluralin	
Rice	Benomyl	Delta, Texas
Seasonings/Spices	Ethylene oxide, Propylene Oxide	Not a U.S. Crop
Soybeans	Acephate, Alachlor, Benomyl, Chlorothalonil, Diflubenzuron, Linuron, Oxyfluorfen	
Sugarbeets	Mancozeb, Maneb, Metiram	
Sugarcane	Asulam, Atrazine, Hexazinone, Simazine	FL, HI
Sunflower Seed	Alachlor	
Tea	Propargite	Not a U.S. Crop
Tomatoes	Benomyl, Captan, Lindane, Oxyfluorfen, PCNB, Permethrin	FL
Wheat	Mancozeb, Methomyl, Tridimefon	KS, ND, NE, OK, SD, WA, OR, ID, CO, MT, UT, WY

**Pesticide/Food Safety Proposals:
Summary Comparison of Key Points
FFDCA**

H.R. 4329	H.R. 1627
Health based standard for tolerance setting. Benefits considered in transition period	Risk/Benefit balancing
Provisions to implement NAS report on children	None
Re-review all existing tolerances and exemptions in 7 years	Re-review tolerances of pesticides in reregistration
Enhanced enforcement	None
None	Preemption of state tolerance setting authority

FIFRA Comparison

	H.R. 4329	H.R. 1627
Registration Sunset	Yes	None
Phase Out/Phase Down	Yes	None
Label Call-In	Yes	None
Reduced Risk Incentives	Yes	None
Support for IPM	Yes	Less extensive
Expanded Record Keeping	Yes	None
Support Minor Uses	Yes	None
Streamline Cancellation	See detailed comparison	See detailed comparison
Streamline Suspension	Yes	Less extensive
Strengthen Enforcement	Yes	None
Export Controls	Yes	None
Increased Fees	Yes	None

National Academy of Sciences Report (1993) Protection of Infants and Children

- Improve data base to evaluate Pesticide Safety
 - more research on age-related changes in animals that may indicate differences in susceptibility of children to pesticides
 - additional studies on hormonal effects, neurotoxicity, immune function, visual system toxicity, in utero exposure
- Improve consumption data for frequently eaten foods
- Improve residue monitoring data for frequently eaten foods

National Academy of Sciences Report (1993)

Protection of Infants and Children

- Strengthen safeguards and assumptions in risk assessments
 - multiple sources of exposure
 - additional safety factors to account for potentially greater sensitivity
 - use probability distribution analyses and other new techniques
- Ensure that all tolerances are based on health considerations, taking into account infants and children

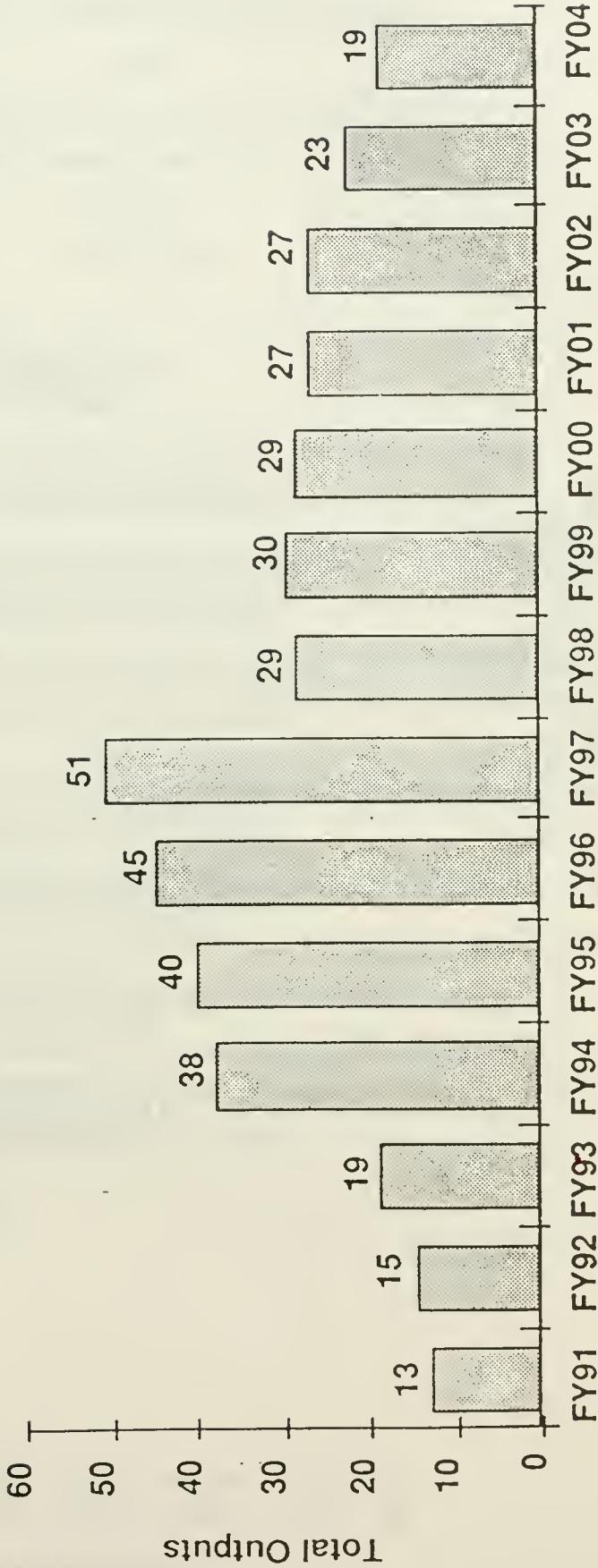
Comparison of Steps Required to Cancel a Pesticide

H.R. 4239

H.R. 1627

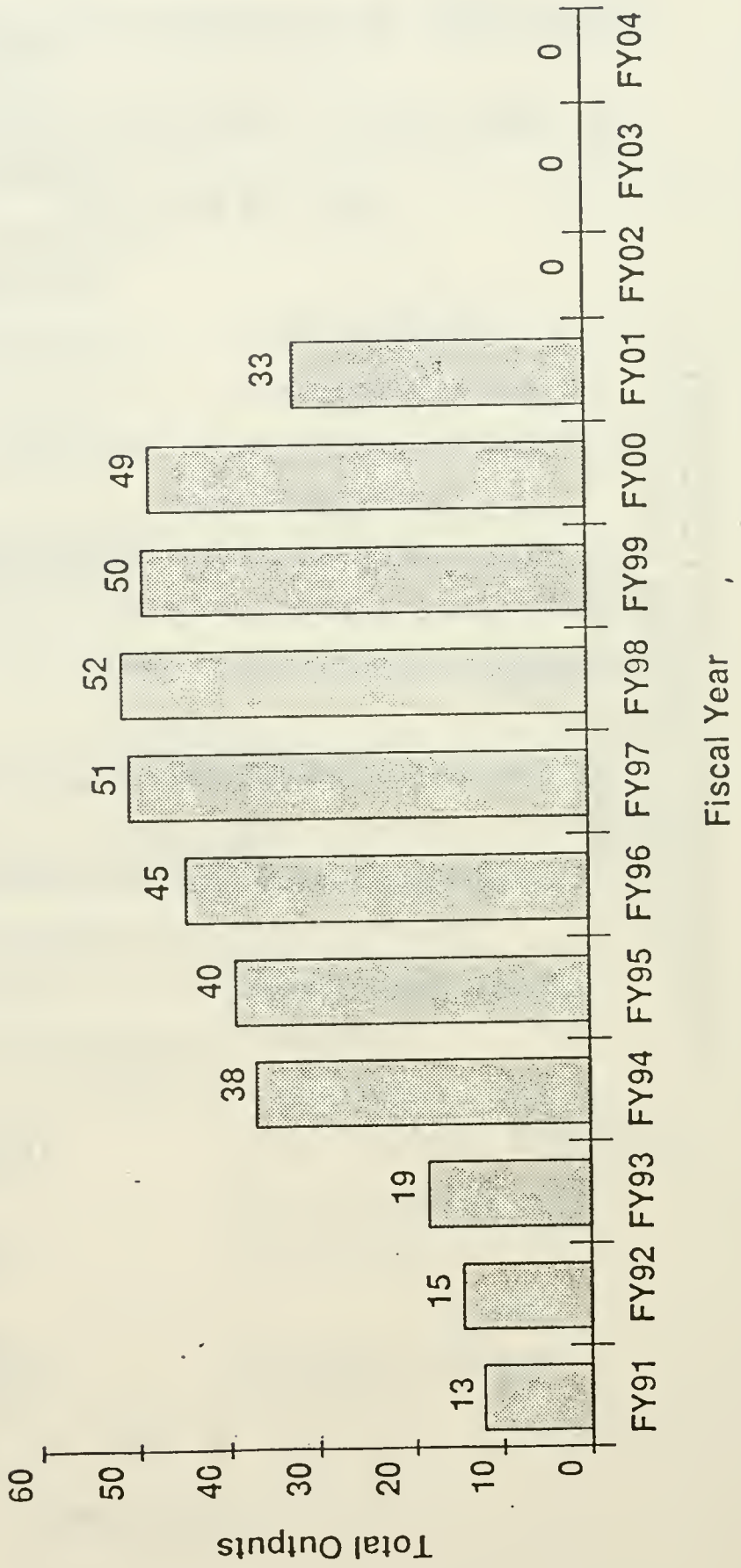
	Formal review of evidence by internal committee
Consultation with Federal agencies and SAP	Prior notice to pesticide registrants and Federal Agencies
	Advance notice of proposed rulemaking
Proposed order for public comment	Notice of proposed rulemaking
Informal public hearing	Informal public hearing
	SAP review, hearing, and report
Final order	Final rule
Judicial review	Judicial review

Projected Reregistration Decisions
without additional funds
under H.R. 4329



Fiscal Year

Projected Reregistration Decisions
with additional funds
under H.R. 4329



TESTIMONY BY CONGRESSMAN RICHARD LEHMAN
BEFORE
THE HOUSE AGRICULTURE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION
REGARDING
FOOD SAFETY

Wednesday, June 15, 1994

Washington, DC

MR. CHAIRMAN: I WANT TO COMMEND THE CHAIRMAN AGAIN, AS I DID LAST AUGUST, ON TAKING A LEAD ROLE IN ADDRESSING THE VERY SERIOUS QUESTION OF FOOD SAFETY. THIS HEARING AND THE ONE LAST SUMMER ON THE LEHMAN/BLILEY/ROWLAND BILL ARE SIGNIFICANT STEPS TOWARD A FULL UNDERSTANDING OF THIS ISSUE AND THE BEST AVENUE FOR REFORM.

IT IS DIFFICULT NOT TO BE BOTH ENCOURAGED AND DISHEARTENED AT THE CLINTON ADMINISTRATION'S RECENT INTRODUCTION OF FOOD SAFETY REFORM LEGISLATION. I AM ENCOURAGED THAT THE THREE LEADING AGENCIES - EPA, FDA, AND USDA - HAVE FINALLY AGREED UPON A PACKAGE THAT CAN BE CLOSELY REVIEWED IN CONGRESS. I AM DISHEARTENED THAT UPON REVIEW, IT SEEMS THEIR LEGISLATION FAILS TO IMPOSE SCIENTIFICALLY BALANCED RISK ASSESSMENTS AND REAL WORLD SCENARIOS IN EVALUATING PESTICIDE RESIDUES.

IN A RECENT TV REPORT THE QUESTION WAS ASKED, "ARE WE SCARING OURSELVES TO DEATH"? HAVE WE CREATED AN ENVIRONMENT WHERE THE REAL RISKS TO PUBLIC HEALTH ARE OVERSHADOWED BY MEDIA ATTENTION DEVOTED TO SENSATIONALIST HEADLINES? IT IS EASIER TO LEAD PEOPLE TO BELIEVE THAT ANY DETECTABLE PESTICIDE RESIDUE, NO MATTER HOW INFINITESIMAL, IS MORE OF A THREAT THAN NATURALLY OCCURRING SALMONELLA, WHEN THE TRUTH IS CURRENT RESIDUE LEVELS ARE SO STRINGENT THAT THEY DO NOT POSE A RISK TO PUBLIC HEALTH.

UNFORTUNATELY, THE ADMINISTRATION IN ITS PROPOSAL OVERCOMPENSATES FOR THE PERCEIVED FEARS GENERATED BY SUCH NEWS STORIES INSTEAD OF ALLOWING ACCURATE RISK BASED SCIENCE TO TAKE ITS COURSE. WHILE THE CLINTON PROPOSAL PROJECTS TO ESTABLISH A "NEGLIGIBLE RISK" STANDARD FOR BOTH RAW AND PROCESSED FOODS, IN ESSENCE IT SETS A STANDARD SO RESTRICTIVE THAT ANY VESTIGE OF FLEXIBILITY IS ELIMINATED.

IN ADDITION, THE PROPOSAL ELIMINATES BENEFITS CONSIDERATION BUT ALLOWS FOR A FIVE YEAR WAIVER IF THE FOOD SUPPLY IS DISRUPTED OR CONSUMER HEALTH IS THREATENED. ON THE ONE HAND THE ADMINISTRATION DRAWS THE CONCLUSION THAT THE ONLY BENEFITS DERIVED FROM PESTICIDE USE ARE ECONOMIC ONES TO THE GROWER, AND THEN IT TURNS AROUND AND ACKNOWLEDGES THAT THE SAFE AND LIMITED USE OF PESTICIDES PROVIDE FOR A HEALTHY, ABUNDANT AND AFFORDABLE FOOD SUPPLY. THE BOTTOM LINE IS THAT BENEFITS ACCRUE TO EVERYONE AND GIVE CONSUMERS SOMETHING THEY HAVE COME TO EXPECT, FRUITS AND

VEGETABLES FREE FROM SCARRING, PEST INFESTATIONS, AND DECAY.

I DISAGREE WITH THE ADMINISTRATION'S APPROACH IN OTHER AREAS AS WELL, INCLUDING THEIR PHASE-OUT PROVISIONS, THE LACK OF UNIFORMITY, EXAGGERATED EXPOSURE ASSUMPTIONS, AND MULTIPLE TOLERANCES FOR A SINGLE PESTICIDE. I DO AGREE WITH THE ADMINISTRATION, HOWEVER, IN THEIR SPECIAL CONSIDERATION FOR INFANTS AND CHILDREN. AS I HAVE STATED REPEATEDLY SINCE THE NATIONAL ACADEMY OF SCIENCES STUDY WAS RELEASED, A CHILDREN'S STANDARD MUST BE INCORPORATED INTO ANY LEGISLATION WHICH PASSES CONGRESS, INCLUDING MY PROPOSAL, H.R. 1627.

IN ADDITION TO THE SUPPORT OF MY COLLEAGUES CONGRESSMEN BLILEY AND ROWLAND, H.R. 1627, THE FOOD QUALITY PROTECTION ACT, HAS BEEN COSPONSORED BY A MAJORITY OF CONGRESS. WHILE THE ADMINISTRATION HAD GOOD INTENTIONS IN BRINGING FORWARD THEIR OWN PROPOSAL, THE FACT REMAINS THAT THE APPROACH PUT FORWARD IN OUR LEGISLATION REFLECTS WHAT IS RIGHT ABOUT OUR CURRENT SYSTEM AND WHAT IS NEEDED TO IMPROVE IT. FLEXIBILITY DOES NOT MEAN WEAK STANDARDS, NOR DOES ACCURATE RISK ASSESSMENT MEAN A LACK OF PROTECTION FOR PUBLIC HEALTH.

CONGRESSMEN BLILEY, ROWLAND, AND I HAVE ASKED CHAIRMAN WAXMAN OF THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT TO MARK UP OUR LEGISLATION, AND I AM HERE TODAY ASKING THE ADMINISTRATION TO WORK WITH US AS WELL TO SEE A

WORKABLE FOOD SAFETY REFORM PACKAGE PASS IN CONGRESS. IT IS TIME TO MOVE BEYOND THE RHETORIC AND AHEAD TO SERIOUS DISCUSSIONS.

I WELCOME THIS OPPORTUNITY TO COMMENT ON THIS ISSUE, AND I LOOK FORWARD TO WORKING WITH THE ADMINISTRATION, AS WELL AS THE CHAIRMAN AND THIS COMMITTEE TO MAKE REAL PROGRESS IN THE COMING MONTHS.

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POSITION STATEMENT

**Testimony of
 Becky Doyle, Director
 Illinois Department of Agriculture
 on behalf of the
 National Association of State Departments of Agriculture
 before the
 House Agriculture Subcommittee on
 Department Operations and Nutrition
 U.S. House of Representatives
 June 15, 1994**

re: Pesticide Regulation Reform

Good morning. Thank you, Mr. Chairman, and members of the Subcommittee. I am Becky Doyle, Director of the Illinois Department of Agriculture and member of the Board of Directors of the National Association of State Departments of Agriculture (NASDA). It is a pleasure to appear before this Subcommittee on behalf of NASDA to discuss the matter of pesticide regulation reform. NASDA is the nonprofit association of public officials representing the Commissioners, Secretaries and Directors of Agriculture in the fifty states and the territories of American Samoa, Guam, Puerto Rico, and the Virgin Islands. As the chief state agriculture officials, NASDA's members are keenly aware of the importance of balancing agricultural production and natural resource conservation on their state's and the nation's economy.

In most cases, under a cooperative agreement with the Environmental Protection Agency (EPA), the state departments of agriculture serve as the lead state pesticide regulatory agency in each state. Therefore, I bring you a unique perspective on pesticide regulations and the reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). NASDA members represent the frontline pesticide regulators who must balance human health and environmental protection with farmers' needs, and face the state and local anxiety over pesticide use and regulation.

BACKGROUND

Under FIFRA, EPA is responsible for registering pesticides using risk-benefit analysis to ensure that pesticide use will not result in unreasonable adverse effects on health or the environment. EPA registers a pesticide only if it determines that it will not cause any "unreasonable risk to humans or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide." Basically, registrations are licenses for specific pesticide uses that state the terms, conditions and cautions of these uses.

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 SECRETARIES AND DIRECTORS OF AGRICULTURE IN THE FIFTY STATES AND FOUR TERRITORIES*

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To register a pesticide, EPA requires the manufacturer to provide health and environmental effects data, product labeling information, a confidential statement of the chemical formula of the pesticide, and child-resistant packaging (if applicable) to EPA's Office of Pesticide Programs, Registration Division. It may take the applicant a few months to several years to gather the necessary data because of the time involved in completing the research required to obtain a registration. The Registrations Division decides to approve or deny the registration after reviewing a complete application. This process can take an average of two years if all the necessary data have been provided, but much longer if data is incomplete and additional data is needed.

Separate legislation guides the setting of tolerances for residues of pesticides registered under FIFRA. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish tolerances — the maximum limits of pesticide residues allowed in or on raw agricultural commodities, processed foods, or animal feeds. Establishing a tolerance is a prerequisite to granting registration for food-use pesticides used in the United States.

In order to establish a tolerance, EPA must determine whether tolerance levels proposed by pesticide registrants will present a health risk to the consumer. Registrants are required to submit toxicology and residue data in their tolerance petitions (applications) to assess possible health and environmental risks, to identify the nature and amount of residue that could occur with proper pesticide use, and to present analytical methods that the Food and Drug Administration (FDA) can use to test the food for residues of the pesticides. EPA scientists (reviewers) use this data to assess the possible health risks of a pesticide's use on food and to determine whether proposed tolerance levels would protect the public health. FDA enforces the EPA tolerances for both domestic and imported produce.

CONGRESSIONAL DEBATE

American consumers can be confident that the U.S. food supply is safe from unreasonable risks presented by pesticide residues. The food products available to U.S. consumers are safe, abundant and economical. NASDA does believe, however, that improvements in our pesticide laws are needed primarily due to advances in scientific technological capabilities.

As the national associations of the state lead pesticide regulatory agencies and officials, NASDA believes that H.R. 1627, the Food Quality Protection Act of 1993, will improve federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a "negligible risk" standard, as recommended by the National Academy of Sciences (NAS). Adoption of this legislation will allow the U.S. to continue to produce the safest, most economical, and most abundant food supply in the world. NASDA strongly supports passage of H.R. 1627 and encourage the House Agriculture Committee to move quickly to favorably report the bill. H.R. 1627 is the most balanced and responsible piece of legislation pending before Congress, and should be the vehicle used by this Committee in reauthorizing FIFRA.

The current debate over pesticide regulation reform boils down to a simple conflict between sound science and emotionalism. Responsible scientists from government, academia, and the industry have shown in no uncertain terms that pesticides can be safely used to provide strong benefits to consumers in the form of a safe, abundant and affordable food supply. Those who worry that any use of pesticides is somehow unsafe — despite overwhelming evidence to the contrary — have been overcome by the sensationalized emotional falsehoods perpetuated by "so-called" experts whose existence depends upon creating fear among the American consumer. These folks believe that pesticides should be eliminated across the board.

In April, the Clinton administration proposed legislation reforming the way pesticides are regulated. H.R. 4329 (amendments to FIFRA) and H.R. 4326 (amendments to the FFDCA) would implement the administration's plan which unfortunately echoes the beliefs of the "chemophobes" lobby. In those bills, emotion and scare tactics seem to prevail over sound science.

The focus of H.R. 4329 and H.R. 4326 is on eliminating the use of pesticides rather than on ensuring their safe use. Some of the proposals put forward by the administration may sound sensible, but most are unworkably rigid and would provide real problems for farmers and food producers. Most importantly, they are ultimately contrary to the best interests of consumers. If the administration's proposals are enacted, it is likely that we will see food scares over hypothetical risks that don't exist in the real world. Adoption of the administration's plan will see the loss of important, safe crop protection tools to farmers, coupled with an increase in food prices and a decrease in availability and quality of food.

The most disturbing situation that has been created by the administration's bills is the likely scenario that no pesticide regulation reform will be passed in this Congress. Mr. Chairman, the 103rd Congress needs to pass pesticide legislation. The industry faces problems created by the conflicting and confusing regulations of FIFRA and the FFDCA, and consumers need to have their confidence in the food supply reassured. Both of these objectives can only be achieved by passage of a bill. Let me stress that I am talking about a bill which improves the situation; one which allows producers to enhance the quality and availability of a safe and nutritious food supply. H.R. 1627 accomplishes that; H.R. 4329 and H.R. 4326 do not.

H.R. 1627 enjoys the support and cosponsorship of some 220 members of the U.S. House of Representatives. I believe that is a bipartisan majority of the House. This committee should report H.R. 1627 to the House floor, and if the other Committee of jurisdiction, the House Committee on Energy and Commerce continues to fail to act on the provisions under its jurisdiction, a discharge petition should be initiated. We as policymakers who understand the importance of this matter must force the hand of those lawmakers who would prefer to either not act or act in a manner inconsistent with sound science.

In the remainder of my testimony, I will concentrate on some of the specific issues which are addressed by the pending legislation.

RIGID NEGLIGIBLE RISK STANDARD

NASDA is specifically concerned that a negligible risk standard not be defined by reference to a specific acceptable numerical risk level, either in statutory language or legislative history. It is essential that EPA maintain flexibility to take account of evolving scientific standards and to consider all relevant safety and exposure information. H.R. 1627 allows EPA to employ its expert judgment unhindered by a numerical straightjacket.

While H.R. 872 (the Pesticide Food Safety Act of 1993 introduced by Representative Henry A. Waxman) eliminate the Delaney Clause, they replace Delaney with a so-called bright-line standard which would prohibit EPA from setting a tolerance under any circumstances for a pesticide posing more than a one in one million lifetime cancer risk based on conservative risk assessment methods. This inflexible standard would unreasonably restrict EPA's expert judgment and would preclude consideration of advances in toxicological science and risk assessment.

The administration's proposal does eliminate the Delaney Clause and replaces it with a narrative negligible risk standard. It, however, creates a dual tolerance system — one tolerance at the farm gate, and the potential for a second tolerance at the supermarket. This new, undefined two-tolerance system does not meet the objective of one safety standard for all foods, and, in fact, will cause increased confusion for consumers as well as regulatory problems.

LIMITATION OF BENEFITS

H.R. 1627 would make clear that EPA may establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that there are countervailing benefits. EPA would be directed to take into account health, nutritional and consumer benefits, including the impact of the loss of a pesticide on the availability of an adequate, wholesome and economical food supply. EPA would be precluded from considering any impact on pesticide manufacturers or distributors. NASDA believes this language must be included in any pesticide reform legislation.

The administration proposal would greatly limit the types of benefits that could be considered in pesticide tolerance decisions, would prohibit the continuation of a tolerance based on exceptional benefits beyond 5 years, and would prohibit any consideration of benefits in tolerance decisions after ten years. The proposal would prohibit EPA from taking into account the value of a pesticide in maintaining an adequate, wholesome and economical food supply unless it could be proven that loss of the pesticide would cause a "significant disruption in the food supply" and would have a profound effect on consumer prices. This limited benefits consideration will expire after the 10-year period. NASDA strongly opposes this narrow benefits standard which would be virtually impossible to satisfy. Prohibition of consideration of benefits for pesticide tolerances would deprive growers of pesticides for which there are no alternatives, would undermine the nutritional welfare of consumers and would not achieve a meaningful risk reduction.

LIMITATION ON USE OF REALISTIC EXPOSURE DATA

NASDA supports the administration's stated goal of using the best available exposure information, including actual pesticide use and residue data, in setting pesticide tolerances. However, the administration's proposal would prohibit the use of actual exposure information (including pesticide use and residue data) and would require use of worse case assumptions unless the registrant could satisfy a heavy burden of proof. Tolerances based on actual exposure data would be subject to discretionary periodic reconsideration and a possible requirement for separate tolerances for raw commodities and processed food. NASDA believes these evidentiary and procedural hurdles would compel the use of exaggerated exposure assumptions and inflated risk estimates in virtually all tolerance determinations.

ACCELERATED TOLERANCE RENEWAL

The administration proposal would generally provide for renewal of pesticide tolerances over a seven year period in conjunction with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) reregistration. Special expedited renewal, over a four year period, would be required for pesticides identified by EPA as having a high risk potential. NASDA believes this accelerated review provision is impractical, could conflict with the FIFRA reregistration process and would give EPA excessive discretion to eliminate valuable food use pesticides without the procedural protections of the FIFRA cancellation process.

"PHASE-OUT/PHASE-DOWN" OF PESTICIDE REGISTRATIONS

NASDA believes it is unnecessary to give EPA entirely new authority to phase-out/phase-down the use of a pesticide where "credible scientific evidence shows a pesticide is reasonably likely to pose a significant risk to humans or the environment." NASDA believes such authority would encourage EPA

to circumvent the FIFRA cancellation process. It would empower EPA to limit or prohibit the use of a pesticide without the external scientific review and procedural protections in the cancellation process, without any consideration of the pesticide's benefits and on the basis of toxicological evidence that is too weak, incomplete or inconsistent to support a complete risk analysis. Phase-out orders would generate damaging adverse publicity, disrupt sales of food products and cause irreparable harm to food producers and consumers. With the modification proposed to cancellation and suspension by H.R. 1627 and the administration proposal, this new vaguely defined concept is completely unnecessary.

CANCELLATION AND SUSPENSION

NASDA believes that statutory changes are necessary to permit EPA to remove hazardous pesticides from the market with reasonable speed. Both the administration proposal and H.R. 1627 would eliminate the adjudicatory hearing process for cancellation procedures, and suspension actions would be decoupled from cancellation procedures. Accordingly, we strongly support these provisions to streamline and speed-up the suspension and cancellation procedures. NASDA believes a provision should be included which would provide an expedited process to retrieve chemicals from the end-user (farmer) which have been cancelled and suspended.

REREGISTRATION PROCESS

The administration proposal calls for a reregistration of all products every 12 years. NASDA supports a reregistration program for all pesticides in order to maintain current and accurate data on products. EPA should be required to provide adequate lead time for the submission of any new data requirements. Additionally, the reregistration process should be made less costly and time consuming, allowing the agency to achieve reregistration in a more efficient manner.

TOLERANCE UNIFORMITY & FEDERAL PREEMPTION

A tolerance uniformity provision is indispensable to preserve EPA's leadership in pesticide regulation and to avoid the consumer confusion and unreasonable burdens on interstate commerce caused by special state tolerance requirements. NASDA strongly supports the uniformity provisions of H.R. 1627.

Pesticide use regulations are best enacted and coordinated at the state level or higher. In this way, conflicting and overlapping regulations may be avoided, and greater access to scientific expertise and input is available. With greater citizen input at the state level, action taken will benefit all residents of the state rather than one isolated town or village. NASDA supports sensible, uniform federal/state regulation of pesticides through passage of preemptive legislation, while allowing local input into the federal/state regulatory process.

FDA ENFORCEMENT AUTHORITY

FDA already possesses ample enforcement power with respect to food violations, including seizure, injunction and broad criminal penalty authority. NASDA does not believe there is a demonstrated need for FDA to have the additional enforcement authority called for in the administration's proposal, such as recall, embargo and civil penalty authority for pesticide tolerance violations. This would give FDA excessive discretionary authority without protecting the due process rights of regulated parties. There is also no reason for FDA to have different enforcement authority for pesticide tolerance violations than for other food infractions.

PRIVATE RIGHT OF ACTION

NASDA strongly opposes the concept of citizen suits against EPA, state regulatory agencies and commercial applicators for any violation of FIFRA as provided for in the administration's proposal. Such a provision is wholly unnecessary and only encourages frivolous lawsuits and disrupts agricultural production. There is no evidence that EPA is unable to adequately enforce FIFRA or that a private right of action provision would meaningfully enhance pesticide safety.

PESTICIDE RECORDKEEPING

NASDA strongly opposes expansion of the 1990 Farm Bill recordkeeping requirements to cover all farmers who apply any general use pesticides as provided for in the administration's proposal. Claims that such a requirement is necessary because USDA does not have sufficient data only points to the failure of data collection, not the failure of farmers to keep records.

As regulators of pesticide application and pesticide recordkeeping, NASDA's members believe such a provision would be absolutely impossible to enforce since those who apply general use pesticides — categorized as such because of their non-threatening environmental nature — do not have to, in any way, be identified.

REDUCED USE

The administration proposal calls for a joint EPA-USDA chaired effort to, within one year, develop commodity-specific pesticide use reduction goals. Under the proposal, the statute would clearly state a policy goal "favoring reduced use and direct federal agencies to take a leadership role in promoting use reduction and IPM [Integrated Pest Management] in their programs." The plan calls for implementation of IPM practices on 75 percent of all production land.

While NASDA believes that IPM programs need to be encouraged, the administration uses the terms "IPM," "reduced use," and "sustainable" interchangeably. IPM programs do not necessarily mean reduced use, but more efficient and effective use of crop protection chemicals. Any legislative goals must clearly define IPM and recognize the difference in the three terms.

NASDA supports the administration proposal calling for the elimination of the prohibition on requiring IPM training as part of the certification and training programs. NASDA also looks favorably on the concept of "prescription use" of certain pesticides in an IPM program only as an alternative to complete loss of the pesticide. Such authority allows the retention of pesticides which may otherwise be cancelled, and should not become yet another mechanism to reduce production tool options. This administration request for "prescription use" further points out the need to allow benefits consideration when registering pesticides.

MINOR USE

NASDA strongly supports the minor use provisions contained in H.R. 967, introduced by House Agriculture Committee Chairman de la Garza (D-TX), and believes this legislation will go a long way toward correcting the problem created inadvertently by the 1988 amendments to FIFRA which have led to the loss of necessary minor use crop protection chemicals. While the minor use issue is an economic one and not a food safety issue, it is extremely important to resolve the issue. The administration proposal includes aspects of the minor use provisions contained in H.R. 967, but it is incomplete and lacks the specificity of H.R. 967. NASDA, therefore, recommends that the language of H.R. 967 be used

in place of the administration's proposal. If a comprehensive bill cannot be worked out, NASDA suggests that H.R. 967 be passed as a stand-alone bill.

STREAMLINE LABEL CHANGES

NASDA believes the administration's proposal calling for an annual uniform labeling effective date allowing registrants to make label changes in a predictable, orderly fashion, would dramatically speed and simplify the process for making changes.

EXPORT OF PESTICIDES

The administration's proposal would ban the export of any pesticide that has been cancelled in the U.S. based on health concerns or environmental reasons. NASDA supports a ban on exports for any pesticide cancelled for health based reasons. NASDA believes this broader prohibition is unnecessary and opposes such a provision. The U.S. does not allow food products to be shipped into the U.S. unless there is a food tolerance, eliminating concerns about non-registered products used in a foreign country and then imported to the U.S. It is further inappropriate for a developed country, such as the U.S., to mandate its environmental agenda on developing countries whose major production goal may well be feeding its people.

STATEMENT OF THE
AMERICAN FARM BUREAU FEDERATION
TO THE HOUSE AGRICULTURE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION REGARDING THE
ADMINISTRATION'S LEGISLATIVE PROPOSAL
FOR PESTICIDE POLICY REFORM

June 15, 1994

Presented by

Mark A. Maslyn
Director, Governmental Relations
American Farm Bureau Federation

The American Farm Bureau Federation appreciates the opportunity to address the issues raised by the Administration's pesticide reform package.

The concern over pesticide policy is intensifying due to several significant forces influencing the regulatory process. These forces include:

- Reregistration mandates created by the 1988 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have forced safe and effective pesticides off the market, not for safety reasons, but for economic reasons. Pesticide losses are impacting growers throughout the country.
- The Les vs. Reilly Ninth Circuit Court of Appeals decision forcing the Environmental Protection Agency (EPA) to enforce the zero tolerance Delaney Clause will dramatically impact the availability of fruits and vegetables, especially if EPA implements its coordination policy.

There are now several different pesticide proposals introduced in Congress. The wide ranging policy options between these bills make it difficult to achieve meaningful progress towards a compromise package. We encourage the subcommittee to move a comprehensive food safety bill this year and point out that a majority of the House has already endorsed the concepts in H.R. 1627, "The Food Quality Protection Act of 1993."

The federal government has primary responsibility for safeguarding the food supply, but farmers are responsible for growing food safely. Growing and raising safe food is our top goal, and we are confident that new research breakthrough and innovations will continue to yield a host of products and agricultural technologies that will help farmers provide an even safer, more healthful and affordable food supply. However, it is critical to remember that until research advances reach beyond the farmgate, policies that arbitrarily reduce pesticide use will affect the supply and affordability of our food supply. These changes will affect low income

Americans first, those who already consume 20 percent less fresh fruits and vegetables than people in higher income brackets.¹

Although criticisms are occasionally directed at our nation's pesticide regulatory system, many seem only intended to undermine public confidence in that system. While a number of reforms to current law are needed, our pesticide policies are fundamentally protective of public health. Any reforms ought to be by design, intended to make a safe system safer and more efficient, not simply more bureaucratic. We share the views of former U.S. Surgeon General Dr. C. Everett Koop when he said:

"I do not know of a single instance where exposure to pesticides on foods in the marketplace is a source of any danger to children or adults. It's a risk of zero."

Dr. Bruce Ames of the University of California at Berkeley adds a word of caution to those who believe that tighter regulation will improve food safety:

"The attempt to prevent cancer by regulating low levels of synthetic chemicals by using worst-case, one-in-one million risk scenarios is not scientifically justified. It diverts resources from much more important risks. Perversely, it decreases consumption of foods that help to prevent cancer."

The Goal of Legislation:

With the purpose and intent of designing improvements to the current regulatory system, there are several important areas that need to be included.

The primary objective of this debate should be to resolve the differences between FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA) as they relate to pesticide registration and the tolerance setting process. The "Delaney Paradox," as described by the National Academy of Sciences (NAS) in its 1987 report, stems from the contradictory regulation in the zero risk Delaney Clause vs. the risk/benefit standard in FIFRA and Section 408 of the FFDCA. The "paradox" in the law is that strict compliance to the Delaney Clause prevents newer, safer but minutely carcinogenic pesticides from reaching farms to replace older, riskier pesticides. Continued adherence to a "zero risk" public policy is neither scientifically credible nor achievable. Coordinating efforts in FIFRA and FFDCA through a negligible risk standard is an essential component for pesticide reform.

¹Steven M. Lutz, David M. Smallwood, James R. Blaylock, Mary Y. Hama, Changes in Food Consumption and Expenditures in Low-Income American Households During the 1980's, USDA/ERS Human Nutrition Information Service, 1993

Second, legislative reform should create a single regulatory standard applicable for both fresh and processed foods.

Third, there is general consensus that the process for removing pesticides determined to present an unreasonable risk to health or the environment takes too long and should be expedited.

Fourth, it is essential that newer, safer products and technologies be developed and approved more quickly to replace those being lost. The lack of replacement products is the most frequently voiced concern by farmers when discussing pesticide policy.

Fifth, the loss of pesticides for "minor uses" is acute and needs to be resolved. Separate legislation, sponsored by Chairman de la Garza and Senator Inouye, would help address this concern. The problem is time-sensitive and needs to be addressed this Congress.

Sixth, is the need to retain the risk/benefit consideration in the registration and tolerance setting process. The most compelling reason of the benefits from pesticide use are described by Nobel laureate Norman Borlaug:

"...[I]f U.S. farmers used the agricultural technology of the 1930s and 1940s to produce the harvest of 1985, they would have to convert 75 percent of the permanent pasture lands in the U.S. or 60 percent of the American forests and woodland areas to cropland. Even this may be an underestimation, since the pasture and forestlands are potentially less productive than the land now planted to crops. This would greatly accelerate soil erosion and destroy wildlife habitats and recreational areas."

The benefits of pesticides accrue to all of society, not just to farmers, and their consideration in pesticide regulatory decisions is critical for a reasoned and coordinated policy. The benefits of pesticide use must be balanced with risks along with the need to feed a world population that is growing by nearly 100 million people every year.

Reducing Pesticide Use

According to National Agricultural Statistics Service surveys, total pesticide use has trended downward since 1982. (Appendix 1) ² This is an important factor that should be considered when setting policy. The agricultural industry has absorbed a

² USDA/ERS Report #622 and USDA/NASS reports "Agricultural Chemical Usage, Field Crops Summary" for 1990, 1991, 1992 and 1993

tremendous efficiency over the last decade. Further efficiencies will come through new technologies and public policies that encourage, rather than impede their development and use. We are troubled by what appears to be a prevailing attitude so heavily weighted toward the removal of products, rather than the introduction of newer, safer replacements. We continue to support innovation in farm practices that will reduce pesticide use. Some of the ideas and options that Farm Bureau has advocated during the past several that will reduce total pesticide use include research to find alternative pest control products including: biological control agents, microbial pesticides, resistance management including the use of genetic engineering, growth regulators and breeding for host plant resistance. We also believe that improvements in pesticide application technology and improved applicator training in reduced use methods will also substantially decrease the need for pesticides without burdensome new regulations aimed at limiting a farmer's control options.

Dollars are needed to fund this type of effort, and the Administration's package does not specify the dollar commitment they intend to seek as part of their use reduction strategy. The need for research dollars for alternatives to pesticides must be the beginning portion of any strategy that has as its goal substantial reductions in pesticide use.

The lack of new monies for research on pesticide reduction projects is critical. Right now, the American Farm Bureau Research Foundation is reviewing eight new research projects totaling \$370,000 that will develop information that farmers can use to reduce pesticide use. One project is to examine biological control for cotton insect pests in Texas. We can finance only a fraction of the research projects that come through our foundation. We estimate that the total dollar commitment to achieve meaningful results for information that farmers can use to reduce pesticide use is \$50 million per year for the next five years.

Already much is being done. In April, at the National Symposium for IPM, over 200 research projects highlighted the vast array of new ideas that will help farmers reduce total pesticide use. Our goal is to build upon the vast and impressive research network anchored through the land-grant university system and create new farming techniques that reduce pesticide use.

Farm Bureau policy for reducing pesticide use is clear and supportive of the following:

1. The widespread promotion and use of integrated pest management (IPM) as a method of reducing costs, risks, liability and total dependence on farm chemicals. Expanded educational and pesticide training certification programs should encourage the adoption of IPM.

2. Continued research and development of pesticides which degrade more rapidly, are less environmentally persistent and are compatible with accepted IPM practices.
3. Increased biological pest control research to determine where biological pest control measures can provide practical and feasible substitutes for non-biological pesticides.
4. A beneficial insects category in USDA's competitive grants program.
5. Improved training programs on the proper handling and safe use of pesticides to ensure the safety of handlers, applicators and agricultural workers.
6. A well funded IR-4 program. Funding for the IR-4 program has crept up, but it is still far short of the \$14 million needed to remove the backlog of outstanding requests.
7. Continued research on the effects of farm chemicals on the environment. Congress can also create incentives for farmers to reduce pesticide use and to find safer alternatives. Incentives could include:
 - Streamlining the EPA registration priorities for EPA. Right now EPA has registration priorities for pesticides that replace Section 18s, for "safer" pesticides, for pesticides that reduce use, for pesticides used on minor crops and for biological pesticides. Because EPA has so many registration priorities, nothing becomes a real priority. We suggest EPA focus in on the areas where farmer's control options are most limited and where risk is highest without classifying registration priorities by pesticide type.
 - EPA should deregulate non-chemical controls and for pesticides generally regarded as safe (GRAS).
 - EPA should work to harmonize state/federal/international research and development incentives for pesticide registrants.

Farmers will continue to reduce pesticide use through new technologies and information transfers that build upon current downward trends in pesticide use. The Administration has taken some positive steps toward meeting some of our goals, but they do not spell out any specific level of commitment. For example, the Administration places reduced risk pesticides on its registration priority list, but does not provide any research monies for their development. Instead, their focus is on regulation and erecting additional barriers to registration and reregistration. This is akin to crimping a funnel, hoping that what trickles out will be sufficient to provide our country with a reliable food supply. That focus should be changed to

concentrate on giving farmers the tools they need to reduce pesticide use. Farmers have proven that when proven new technologies become available, they will adopt them.

Building Upon Our Current Food Safety System

The central question to the entire pesticide/food safety debate is "How can our current food safety system be improved?" This is also the question Congress must answer if it expects to resolve the gridlock surrounding food safety. Our perspective is clear. While our current system needs improvement, the evidence is overwhelmingly in favor of building upon what we have, rather than starting from scratch.

There is a lot of good news for the American food consumer: the supply of food is safe and bountiful, quality is unparalleled, variety is ever-expanding and prices are reasonable. The American farmer/government/university food production system is unrivaled - our quality of life and health provide sufficient evidence and argument to build upon our current system.

It is important to note that while modern technology has greatly improved our ability to measure or detect the tiniest trace of chemicals in food, we have had no increase in our ability to make these numbers useful or meaningful to the food policy process. This results in periodic food safety scares. They do not mean that our current system needs an overhaul. Residue testing is a good example.

In May of 1991, the U.S. Department of Agriculture implemented the Pesticide Data Program (PDP) to collect objective, comprehensive data on pesticides in fresh fruits and vegetables. In April, they released results from 1992.³ In 1992, the PDP analyzed 5,750 fruit and vegetable samples and found that 61.2 percent of the samples contained detectable residues.

At first glance, this may seem high, but closer examination reveals otherwise. Only 63 of 5,750 samples contained residues in violation of the tolerance. Keep in mind that the tolerance is the safe and legal limit of the amount of pesticide residue that may be present in raw or processed foods. Fifteen of those 63 samples with illegal residues were from imported food. Fifty three examples had residues where no tolerance was established by the EPA. Only 10 samples contained residues in violation of the established tolerance.

³ Pesticide Data Program (PDP), Summary of 1992 Data, U.S. Department of Agriculture, Agricultural Marketing Service, 1994

When residues were found, 92.8 percent of all residues were below 1 part per million, 55.7 percent were below 100 parts per billion, with 8.5 percent below 10 parts per billion.

The PDP also compared detected residues with the pesticide tolerance for 40 pesticide/commodity pairs. Of those pairs, only five pairs resulted in a mean concentration which exceeded 10 percent of the tolerance, with the highest value representing just 22.5 percent of the established tolerance. In other words, a minimum tenfold safety margin could be added to the tolerance for 35 of the pesticide/commodity pairs and the mean detection would be under the established tolerance. For some pesticide/commodity pairs, the safety margin could be increased by as much as 200 times and residues would still be under tolerance. Regrettably, some groups have used our increasing ability to detect as a means to generate interest among the media and fear among the public.

Clearly, this data indicates that our current food safety system works and changes need to build upon what is already a solid foundation.

Similarities Between Administration Bill and H.R. 1627/S. 1478

Farm Bureau strongly supports the "Food Quality Protection Act of 1993," (H.R. 1627 and S. 1478). It is a comprehensive proposal that amends both FIFRA and FFDCA with a single negligible risk standard for fresh and processed foods. We urge the committee to mark up H.R. 1627. For the purpose of furthering discussion, we have listed some of the conceptual areas where there is similarity between the Administration's plan and H.R. 1627. They include the following:

1. Label Call-In

Farm Bureau could support the concept of a label call-in program as long as this authority extends only to minor label changes. Label call-in should not remove crop uses or substantively alter the use of the product. While a label call-in program might be one area where agreement could be forged, the current language of the Administration bill is much too broad and gives EPA virtually unlimited authority to make changes.

2. Integrated Pest Management

Last September, the Administration set a goal of implementing IPM programs on 75 percent of crop acreage by the year 2000, but the new bill offers no such numerical goal. To accomplish their IPM goals, FIFRA's current prohibition on requiring IPM training as part of the certification program will be repealed. Pesticides critical for IPM programs, but which may pose higher risks, may be available for prescription uses. Such changes are encouraging but must be accompanied by an on-going

commitment to overcome numerous impediments. Farm Bureau is fully committed to working with the Agency on this.

The bill does not identify any specific actions or federal funds to develop research and new technologies that will allow farmers to achieve wider adoption of IPM. We strongly encourage that additional federal research monies be appropriated for IPM research and technology transfers.

3. Pesticide Use Data Collection

The Administration plans to collect additional pesticide use data to improve pesticide regulatory decisions. Farm Bureau supports the collection of actual residue data from farm products to establish use patterns for pesticides. This data should be used in the pesticide registration, reregistration, cancellation and special review process only. We cannot support the Administration's mandatory record keeping proposal for all pesticides, due in large part to the punitive nature of their plan that includes inspections of records by federal employees and others. We also find it inconsistent that the legislation emphasizes data collection, yet fails to allow, for practical purpose, the use of that data in determining exposure assumptions.

We also support the collection of additional data that will ensure the safety of handlers, applicators and agricultural workers, but oppose the Administration's plan to expand the role of the Health and Human Services Administration "related to the health effects of pesticides on farm workers." As stated previously, improved worker training programs will help improve worker safety.

4. Minor Use Pesticides

Farm Bureau is a member of the Minor Crop Farmer Alliance and strongly supports the "Minor Crop Pesticides Act of 1993," introduced by Representative de la Garza and Senator Inouye. The Administration recognizes the minor use problem and supports some of the reforms advocated by the de la Garza/Inouye package. Under their plan, exclusive data use will be extended for two years instead of 10. IR-4 funding will be expanded. Transitional registrations will continue until reregistration is complete for specific pesticides. These reforms move toward our objective, but are weaker than those in H.R. 967. Farm Bureau encourages the Administration to include the de la Garza/Inouye bill as part of their package.

5. Reduced Risk Pesticides

We support the effort to establish criteria for reduced risk pesticides. We also support provisions which create incentives for registrants to develop safer pesticides and farmers to use them once they are registered. We support the Administration's plan to give registration applications that meet the new criteria priority and

expedited review and thus, qualify for exclusive data use. We also support conditional registrations for biologically-based pesticides before a full data set is developed.

We encourage the Administration to seek additional research dollars to find lower risk alternatives. The Administration's commitment to reduced risk pesticides needs to be clearly spelled out.

6. Pesticide Cancellation

We support changes in FIFRA, outlined in H.R. 1627, that will streamline the process for cancellation of potentially dangerous pesticides. The existing cancellation process is lengthy and hampers EPA's ability to remove potentially dangerous pesticides from the market in a timely manner. The cancellation process should move quickly if a full and complete analysis of the data supports the cancellation of specific pesticide products. Farmers rely on the registration process for safe, effective pest control products. If new evidence supports the cancellation of products, that process should move quickly. Much of the integrity of pesticide registration relies on the ability to deal quickly with "bad actors."

Provisions of the Administration's Plan Farm Bureau Cannot Support

Regrettably, Farm Bureau cannot support many of the Administration's proposed changes to FIFRA and FFDCA. Despite numerous meetings with the Administration with the objective of forging a legitimate compromise, the proposal fails to strike anywhere near a common center. The proposal is excessively focused on strengthening the regulatory side of pesticide policy rather than on measures that help farmers reduce pesticide use and risk. Our specific concerns with the Administration plan are outlined below.

1. Loss of Benefits Consideration in the Registration and Tolerance Setting Process

The Administration will not consider the benefits of a pesticide if risk exceeds their risk standard and will eventually phase out benefits consideration altogether. A risk-only approach to pesticide regulation does not reflect the contribution of pesticides to our food supply. It is important to note the benefits society derives from the safe and judicious use of crop protection chemicals. These benefits include:

- Agricultural chemicals reduce the risks of crop failure and stabilize food production. Farm Bureau has catalogued a list of crops affected by the loss of minor use pesticides to demonstrate the role pesticides play in food production. "The Loss of Safe Pesticides for Minor Crops" cites examples from 32 states, and we have provided the subcommittee with copies of the report.

We have also submitted research from Texas A&M University entitled "The Economic Impacts of Reduced Pesticide Use on Fruits and Vegetables" ⁴ as further evidence of the benefits derived from pesticide use.

- Agricultural chemicals allow food to be produced on less land. Land that would otherwise be needed for food production can be devoted to wildlife habitat and other beneficial uses. Pesticides also allow environmentally fragile lands to be idled. Fewer farmed acres reduces the amount of water needed for irrigation.
- Agricultural chemicals prevent soil erosion resulting from increased cultivation to control weeds.
- Agricultural chemicals reduce farm costs. Reduced costs allow us to compete in world markets. Lower farm costs also translate to lower food costs which encourage consumption of foods important to health. There is a growing body of evidence that greater consumption of fruits and vegetables help prevent cancer. Higher food costs are likely to limit the production of foods we should be consuming most. In 1988, the Surgeon General's Report on Nutrition and Health said this:

"Some epidemiologic evidence suggests that frequent consumption of vegetables and fruits, particularly dark green and deep yellow vegetables and cruciferous vegetables, may lower risk for cancers of the lung and bladder as well as some cancers of the alimentary tract."

- Agricultural chemicals allow food to be grown domestically, rather than depending on imports where we have little to no control over food production methods.
- Agricultural chemicals improve the quality and storability of food. Consumers can expect more perishability at the marketplace as a result of pest infestation and consumer rejection of products with poor appearance and quality if farmers are forced to arbitrarily reduce pesticide use. Consumers can expect poorer quality of foods that are typically stored for long periods, like apples. High quality foods are essential for meeting export standards as well. Customer countries will restrict U.S. products if they do not meet quality or phytosanitary standards.

⁴ Ronald D. Knutson, Charles R. Hall, Edward G. Smith, Samuel D. Cotner, John W. Miller, Economic Impacts of Reduced Pesticide Use on Fruits and Vegetables, 1993

- Agricultural chemicals have substantially decreased farm labor requirements, as well as associated costs. History has shown that it is difficult to attract labor to agriculture due to the often difficult working conditions.

The Clinton plan would not permit approval of any pesticide tolerance with greater than one in one million lifetime cancer risk, regardless of benefits. Ignoring the benefits of crop protection chemicals in the registration process presumes that a widely available and affordable food supply plays no role in human health. In choosing to eliminate benefits consideration, EPA has failed to make its case. Why after three decades is this change of course warranted? Where is the evidence supporting this? What measurable gain in food safety will be seen from this? Farm Bureau supports the consideration of both the risks and the benefits of pesticides in the evaluation of chemical products and cannot support the Administration's proposal.

2. Negligible Risk

The Administration's plan defines negligible risk as one-in-one million cancer risk over a lifetime using 100 fold safety factors. This rigid safety standard ties food safety down to an inflexible standard that cannot be changed with improvements in science and technology. In some cases, the new standard may be worse than the Delaney Clause due to its inflexibility.

It is impossible for Farm Bureau to predict the impact and loss of current registrations if EPA were forced to implement the new standard. We urge the subcommittee to ask EPA to analyze the outcome to current tolerances and registrations and ultimately, the impact to food production under their proposed negligible risk standard.

Farm Bureau supports a flexible negligible risk standard. One of the primary lessons from Delaney is that rigid standards do not adapt to changing science. A flexible risk standard recognizes that risk assessment is constantly evolving and improving. A flexible standard that allows the EPA to update its methodology to keep pace with the developing science of risk assessment is an essential part of a coherent food safety policy.

3. Tolerance Uniformity

The Administration's plan has no provision for tolerance uniformity. States would be allowed to set pesticide tolerances that are more restrictive than federal standards. Farm Bureau supports provisions that prohibit states from establishing pesticide tolerances that are more stringent than federal tolerances, unless special local conditions warrant consideration for a more restrictive tolerance.

4. Exposure Analysis

Farm Bureau supports the use of actual pesticide use data in exposure analysis, and we strongly disagree with the Administration for its intention to use exaggerated exposure assumptions, such as 100 percent of crop treated at full label rated and minimum pre-harvest intervals. What is the value in the data collection provisions if worst-case assumptions are mandated anyway? This provision will guarantee continuation of overstated risk estimates. We also disagree with provisions which would give EPA the authority to set multiple tolerances for different points in the food chain, including at the farmgate and in the grocery store based upon exaggerated exposure data. This will create a regulatory nightmare for everyone involved in food production and marketing while doing nothing to improve food safety.

5. Phase-Out/Phase-Down

Farm Bureau disagrees with the Administration's plan that would allow EPA, without a complete scientific review, to phase-out/phase-down a pesticide by imposing production caps or eliminating uses. It is impossible to comment on the potential effects of this provision without knowing what current registrations the Administration has targeted as likely candidates for regulation under this provision. This new authority is extremely vague and loose. It is unclear what situations this is intended and why existing or expedited cancellation and suspension authority are inadequate.

7. Enforcement Provisions

The Clinton plan spells out a broad new set of enforcement guidelines, including requiring all private applicators to become certified applicators. The current requirement for farmers to keep records of restricted use pesticides only will also be changed to include all pesticides.

Farmers will be required to notify EPA where records are maintained and will be required to furnish EPA a copy of the records on written request. Any employee of the U.S. or states who has been designated by the EPA will have the authority "to enter and inspect" to obtain: a) Samples of any pesticide; b) Copies of any records or of any pesticide labels; c) Copies of documents related to compliance under the Act; d) Copies of any data or samples of any specimens involved in the testing of any pesticide; and e) Samples of any places where pesticide residues may be found, including without limitation, agricultural commodities, animals, pests, soil, or water.

The Administration's enforcement efforts seem to rely on intimidation and harassment of farmers based upon the authority to enter and obtain confidential

business information from farmers. These provisions are excessive and unwarranted and Farm Bureau strongly opposes them.

8. Citizen Suits

Farm Bureau opposes provisions in the Administration's plan that provides an opportunity for citizens to ask the EPA "to commence an action against any agricultural producer who is alleged to have violated...any provision of the Act." Enforcement by citizen action implies that the government is incapable of enforcing the law by itself and needs help from citizens to uphold the law. Citizens are not trained or qualified to properly enforce or even report on suspected violations of federal pesticide law and is a provision that Farm Bureau strongly opposes. If Congress sees fit to create federal laws that the government cannot enforce, then certainly citizen action is not the answer. Allowing citizen action against farmers is unnecessary, punitive and forces farmers to defend themselves against alleged violations that will be prosecuted by the federal government.

9. Suspension

The bill would eliminate the right of a registrant to an expedited hearing on a proposed suspension order. EPA would be authorized to suspend a pesticide registration for 180 days without a hearing and without requiring a notice of intent to cancel. This provision would deny registrants a fair expedited hearing and would create unnecessary confusion and uncertainty for farmers who market products containing a suspended pesticide. For these reasons Farm Bureau opposes the bill's suspension provisions.

Conclusion

The concern over food safety is a concern that farmers share. But our view is tempered by the knowledge that pesticides remain an essential tool to control pests. Pesticides, for the foreseeable future, will continue to be used to protect our food supply from insect, disease and weed pests. Crop protection products themselves will also change by encompassing more than just chemical control agents. Farmers are farming differently today than they were 10 years ago or they were one year ago. Farmers learn something new every day, which changes the way they farm tomorrow and the way they use pesticides. Standards that are based on the belief that simply canceling pesticides improves food safety ignores the real world damage that pests inflict upon crops and ignores the changes in farming practices and integrated approaches that farmers are using to reduce pesticide use.

Since 1958, our nation's food safety system has been governed by the Delaney Clause, a well intended but unachievable statute. Although science and technology have evolved with time, our regulatory system has not kept pace.

Driving this debate is the Les vs. Reilly court decision which will require the EPA to enforce the Delaney Clause and take action against pesticides that might be carcinogens. The immediate need to replace the Delaney Clause is real. EPA has chosen to place the burden and responsibility for action squarely on the Congress, to avoid the potentially harsh effects of a strict policy application of the Delaney Clause. However, in shifting the burden to the Congress, the Agency has chosen to ignore other non-legislative remedies that could avoid or soften the impact on farmers and consumers. In fact, they have taken every action to increase the potentially harsh economic impact upon the farm community in order to create pressure on Congress to reform the law. We believe this to be a particularly unnecessary and irresponsible action with unknown consequences to agricultural producers.

The impacts of Les vs. Reilly case and the Delaney Clause must be avoided. Neither farmers nor consumers will benefit from the train-wreck policy that is currently being pursued.

Thank you for the opportunity to comment.



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TESTIMONY OF TOM STENZEL

Mr. Chairman, thank you for the opportunity to appear on this panel today to testify on an issue of vital importance to the fresh fruit and vegetable industry. My name is Tom Stenzel and I am President of the United Fresh Fruit and Vegetable Association (United). United has 2,000 members that are grower/shippers, brokers, wholesalers, food service distributors and operators, retailers, allied suppliers and related educational and scientific organizations in the United States and abroad.

Mr. Chairman, it is my very strong desire for this Congress to pass legislation which provides for comprehensive reform of our nation's pesticide laws. I know time is short, but United is ready to sit down now with interested groups and begin discussions on pesticide legislation. We want an improved cancellation process to more quickly deal with problem pesticides, Delaney reform, a resolution to the minor use problem, and a process that provides for speedier approval of a new generation of pesticides such as biologicals. I believe that these and other issues can be addressed in a bill that passes this year.

The nation's fruit and vegetable producers, and those businesses involved in the shipping, transportation, distribution and retail of produce want to strengthen and broaden the regulatory authorities of the Environmental Protection Agency (EPA). The credibility of EPA as a strong regulator is in need of repair. Restoring public confidence in our nation's system of regulating pesticides means providing EPA the ability to more quickly restrict or eliminate the use of problem pesticides and reforming the outdated Delaney clause.

Many of us in the agricultural community awaited with anticipation the Administration's pesticide legislation. Despite the overwhelming support from our industry for H.R. 1627 and S. 1478, and the support of 222 members in the House of Representatives and over 20 Senators for these two bills, it is well understood that neither bill is likely to escape the jurisdictional trap that now contains them. For this reason, we sincerely hoped the Administration would craft a bill to break the logjam that characterizes this issue: they failed.

Mr. Chairman, the Administration's bill has done little to further the prospects for passage of pesticide legislation. To be fair, the Administration's bill does address many important issues and attempts to bring form to numerous regulatory concepts deserving discussion. However, the issues and concepts raised by the bill are ill served by this vehicle. The bill's many flaws preclude its use as a basis for compromise or negotiation.

Both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) must be addressed by legislation that attempts comprehensive reform. Amendments to one law, in isolation to the other, will not accomplish the job of overhauling the system of regulating pesticides. FIFRA and the FFDCA serve very different functions--FIFRA regulates the use of pesticides, while FFDCA regulates pesticide residues in food. Despite these different purposes both laws must operate in harmony. EPA cannot administer a pesticide regulatory program based upon conflicting laws. The criteria for approving and regulating the use of a pesticides must be consistent with the standards governing the presence of pesticide residues in food. It is for this reason that the Delaney clause is so problematic, because it represents a standard that is antithetical to the risk-benefit standard contained in FIFRA and section 408 of the FFDCA.

United strongly supports the risk-benefit principle. Congress intended pesticide regulatory decisions be made in the context of benefit considerations. The acceptability of risk is determined by countervailing benefits associated with the use of a pesticide. FIFRA § 2(bb) defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." The Administration's pesticide legislation seeks to limit substantially the consideration of benefits, both in FIFRA and the FFDCA.

Furthermore, the Administration's legislation would reconstruct the pesticide regulatory system to substantially limit opportunities of stakeholders in a pesticide to due process. This is a critical point. The essential problem, in attempting to streamline procedures that would allow the Environmental Protection Agency (EPA) to more quickly restrict or eliminate the use of a pesticide, is a need to balance a requirement for adequate justification of a regulatory action and due process, against the requirement for expeditious action in light of a concerned public and possible marketplace rejection of the pesticide or foods bearing residues of the chemical.

The Administration bill grants sweeping authority to EPA to restrict or eliminate the use of pesticides, such that there would be little regulatory predictability or protections against overly aggressive regulatory actions. This is certain to create more instability in the marketplace, not less, as food wholesalers, processors and retailers learn to fear the increasingly likely prospect of possessing inventories of foods bearing residues of pesticides tainted by an adverse regulatory decision. Also, we fear that imposing severe limitations on opportunities for pesticide registrants to defend their products--after making the huge investment to receive approval for the use of the product--will directly affect the willingness of

pesticide chemical manufacturers to invest in research, development, money and time involved in registering pesticides.

Mr. Chairman, what follows in my testimony is a review of some of the provisions contained in the Administration's bill and our concerns.

Phase-out, Phase-down Authority--This proposed authority is flawed in concept and cannot be repaired. We strongly oppose the idea of interim measures which phase-out or phase-down the use of problem pesticides. If a pesticide is judged to be unreasonably risky, then EPA should take decisive action to restrict or eliminate the use of that pesticide. Phasing-down or phasing-out use provides no comfort to the consumer and would be terribly disruptive to our industry.

The bill would grant EPA the authority to "restrict, reduce or eliminate" the use of a pesticide where "credible scientific evidence indicates that use of the pesticide is reasonably likely to pose a significant risk to humans or the environment." This authority would allow EPA to limit or prohibit the use of a pesticide without the external scientific review and procedural protections guaranteed under the cancellation process. Furthermore, EPA would not have to consider the benefits of the pesticide and could act based upon evidence that was too weak, incomplete or inconsistent to support a cancellation.

A central reason for pesticide reform is to prevent future Alar and EDB-like scares. Yet, this provision would precipitate precisely such public alarm. In effect, EPA would announce that a pesticide is problematic, but then take incomplete action by phasing-out its use over a 5 year period--a not very comforting scenario. Streamlining the cancellation process would assure that pesticides shown to pose unreasonable risks are removed from the marketplace promptly.

Whistle Blower Protection--The Administration bill would provide broad legal rights to any employee alleging termination of employment or adverse treatment in retaliation for bringing a legal action, or threatened legal action, for an alleged FIFRA violation. Under this authority an aggrieved employee would be authorized to prosecute a complaint before the Department of Labor and, if unsuccessful, to bring a lawsuit in Federal court for reinstatement, damages, costs and attorneys' fees. We view this provision as providing aggrieved individuals opportunity to harass employers or unjustly protect employment status, with no identifiable benefit to public health.

Citizen Suits--The bill would authorize any person to bring a lawsuit in Federal court against EPA, a pesticide registrant or any pesticide user, except for

farmers, for any alleged violation of FIFRA or of any EPA pesticide regulatory requirement. This provision would increase the litigation burdens of Federal courts, would interfere with EPA's enforcement prerogatives and would subject pesticide producers and users other than farmers to expensive and burdensome lawsuits. It is not clear to us if fruit and vegetable producers applying pesticides during post-harvest operations, i.e., in the packing shed, would be subject to the citizen suit provision. Nonetheless, we see no useful purpose for this provision.

Cancellation Procedure--The bill would streamline cancellation procedures by eliminating opportunity to an adjudicatory hearing and narrowing the scope of benefits that EPA must consider to a "general analysis of the impact of the proposed action on consumers, retail food prices, production of agricultural commodities, and otherwise on the agricultural economy." The Administrator would be required to provide opportunity for public comment on a proposed cancellation order for a period of not less than 90 days. Further streamlining is achieved by providing the Administrator discretionary authority to provide interested parties an opportunity to an "informal hearing" and waiving any requirement for review of the proposed cancellation order by the Scientific Advisory Panel is included.

Changes to the cancellation procedure are the most important reform proposed to FIFRA. This is the central requirement of any change to FIFRA. We need a process that more quickly restricts or eliminates problem pesticides and that is responsive to public concern. The intent in reforming the cancellation process should be to retain the current risk-benefit standard contained in the "unreasonable adverse effects" definition, while clearing away the procedural hurdles that impede quick, decisive regulatory action. In other words, the Agency should be required to prepare as thorough and convincing a justification for cancellation as under a reformed cancellation process as under current law.

By eliminating cross-examination before an Administrative Law Judge and relying upon the process contained in the Administration's bill, the burden to justify the proposed cancellation is substantially lowered--even though the risk-benefit standard remains unchanged. The reason being the Agency would not have to justify and defend its proposed action under the test of cross examination.

Mr. Chairman, let me offer a comparison. If you never had to respond to oral questioning during your reelection campaign, but could answer all inquiries through mail, then clearly the burden on you to justify your record and actions as a Representative before your constituents is substantially less than if you have to participate in a debate before that same audience. Similarly, eliminating cross-examination makes EPA's task vastly less arduous in canceling a pesticide.

For this reason, we strongly support the cancellation provision contained in H.R. 1627, the Lehman-Bliley-Rowland bill and object to the Administration's proposal. H.R. 1627 makes certain that EPA will only propose cancellation actions with adequate justification, while eliminating the burden of cross-examination.

Suspension Procedure--The bill would eliminate the current right of pesticide registrants for an expedited hearing on a proposed suspension order. EPA would be authorized to suspend a pesticide registration without a hearing for 180 days. If a cancellation proceeding was not initiated within the 180 day period, the suspension would remain in effect until the completion of the cancellation process. This provision would give EPA excessive discretionary authority, would deny registrants a fair hearing and would cause irreparable harm to food producers who market products containing a suspended pesticide. Post-suspension court review, as provided for in the bill, would not offer a meaningful substitute for a pre-suspension hearing.

FFDCA Amendments:

Pesticide Tolerances--The bill will expand the requirement to establish tolerances under section 408 of the FFDCA. Any "pesticide chemical residue", which includes any residue of the pesticide or component of such chemical, or any other substance present in or on the commodity or food as a result of the metabolism or other degradation of a pesticide chemical would require a tolerance. Currently, EPA is afforded the discretion to determine which inerts and degradates require tolerances. The expanded requirement for tolerances or exemptions for pesticide chemical residues will substantially increase EPA's workload and place additional data burdens on registrants to support pesticide registrations and tolerances. We fear the new burdens will adversely affect the availability of minor use pesticides.

Risk Standard--The Administration bill would replace the application of the Delaney clause to pesticides and impose instead a conservative and rigid risk standard for pesticide tolerances. No tolerance could be established unless it is determined that the residue permitted by the tolerance is "safe". The term "safe" is defined to mean there is "a reasonable certainty that no harm will result from all anticipated exposures to such residue" and to take into account "special vulnerabilities of children and sensitive sub populations." A separate safety standard is established for potential carcinogens, broadly defined to include any pesticide found to induce cancer in man or animals, or found to pose "a potential dietary risk of cancer in humans".

In assessing risk, the bill requires the Administrator to "fully account" for available information on: the probable consumption of foods by significant sub populations; the cumulative effect of the pesticide residue and other chemically or pharmacologically related substances in the diet, and other ways in which the consumer may be exposed to the pesticide; and, valid scientific data regarding estrogenic or other hormonal effects associated with the pesticide.

A special requirement to ascertain and publish a finding of safety for infants and children with respect to a tolerance is required. Furthermore, an additional 10-fold margin of safety must be applied in establishing a tolerance to protect infants and children, unless reliable data permit a determination of another different margin of safety. This requirement would require a 1,000 fold margin of safety for threshold effects—10 times more than typically required.

No one disputes the necessity of a standard that is protective of public health. I am also confident that no person in this room would contemplate advocating a standard that did not adequately protect infants and children from the risks associated with pesticides. However, the Administration's proposed risk standard has devolved into political gamesmanship of who can offer the most protective standard for infants and children. United believes pesticide legislation must provide very clear direction to limit the risks from pesticides to negligible levels and that EPA must be held accountable for implementing that standard. Adopting the overly prescriptive risk standard proposed by the Administration would repeat the same mistake made by Congress in adopting the Delaney amendment in 1958.

Exposure Assumptions--In establishing a tolerance the Administrator is directed to assume that foods bear pesticide residues at the level established by the tolerance closest to the time the food is purchased. The Administrator may utilize percent of crop treated information, but only if the data relied upon are: reliable and valid; do not underestimate exposure for any significant sub population group; do not underestimate exposure for any particular area; and, there is provided periodic reevaluation of the estimate of anticipated exposure.

In addition, to the above mentioned requirements, additional considerations must be satisfied with respect to exposure for infants and children to include an assessment of available data on food consumption patterns; neurological differences between children and adults, including the significance of in utero exposure; and, the synergistic effects of different pesticides.

United believes the constraints imposed upon the use of realistic exposure data mean that EPA would not use such data and that risk assessments would be based upon assumptions of 100% of the crop being treated, and that residues in

foods were present at tolerance levels. Such assumptions would massively overstate risk resulting in the loss of uses for many currently approved pesticides or limiting potential uses for future approved pesticides. This would further compound the minor use problem.

Renewal of Tolerances--At present, pesticide tolerances are reviewed concurrent with the reregistration process for pesticides. The Administration bill would require a speed-up of the process. So that by three years after the date of enactment the Administrator must determine whether or not 75% of the tolerances or exemptions in effect satisfy the requirements of section 408 of the FFDCA, and 100% by four years after enactment.

The requirement of tolerances for a broader universe of pesticide chemical residues (to include inerts and metabolites) means the agency may have to make 600 to 1,000 tolerance reviews or evaluations. An enormous burden for an agency already behind in its responsibility to fully reregister pesticides by 1997.

In United's judgment, decoupling the registration process from tolerance review makes little sense.

Multiple Tolerances--The Administration bill would authorize EPA to establish multiple tolerances for a pesticide on a commodity at different points in distribution (i.e., a farm gate tolerance and tolerance for foods after processing or at the point of retail). This authority appears intended to solve the problem created by a requirement elsewhere in the bill to assume, for purposes of risk assessment, that residues are at tolerance levels. Tolerances for processed foods or foods at retail would be lower than farm gate tolerances, since residue monitoring data indicate that pesticide residues diminish as foods near the point of consumption.

The new multiple tolerance requirement would mean additional data burdens for registrants and complicate Food and Drug Administration (FDA) enforcement efforts. Furthermore, multiple tolerances may lead to skewed perceptions of the relative safety of fresh fruits and vegetables and processed foods. A higher separate tolerance for a fresh item may lead consumers to falsely assume a greater risk with the fresh produce and place fresh produce at a marketing disadvantage. Also, while separate tolerances may be established for produce sold at retail (grocery stores, etc.) it is unclear what the enforceable tolerance would be for produce sold at points closest to the farm (i.e., roadside stands and farmers' markets) where residues may not have volatilized or degraded to the same extent as produce sold in a grocery store. United believes that this provision is unnecessary and overly complicate enforcement.

Benefits--The Administration bill limits and phases out the consideration of benefits in pesticide tolerance regulatory decisions. Tolerances that could not satisfy the new risk standard would be revoked, unless the pesticide provided extraordinary benefits to public health, or the loss of the pesticide would entail "significant disruption in domestic food production". Ten years after enactment of the bill no consideration of benefits in tolerance decisions would be permitted. Prohibiting the consideration of benefits makes no sense. The explicit consideration of benefits provides useful guidance to the Agency. It assures the public that regulatory decisions are made in the context of considering the benefits to society. The Agency has consistently argued that benefits have not been relied upon to retain uses of unreasonably risky pesticides, so it is clear that benefits do not impede the proper and timely consideration of risk concerns.

Tolerance Uniformity--The Administration's bill fails to include a pesticide tolerance uniformity provision. A tolerance uniformity provision is indispensable to the preservation of EPA's leadership in pesticide regulation and necessary to avoid consumer confusion. The lack of uniformity between the states would impose unreasonable burdens on interstate commerce. It makes little sense to expend the time and effort to enact pesticide regulatory reform, overhaul the regulatory process and then fail to establish the primacy of federal pesticide tolerances.

FDA Enforcement Authority--The bill would grant FDA broad new enforcement powers, including recall and embargo, and civil penalty authority, with respect to tolerance violations. If an officer or employee of the Department of Health and Human Services "has reason to believe that any article of food is adulterated . . . the officer or employee may order the food detained for a reasonable period which may not exceed 20 days (or 10 days, in the case of perishable food)." The 10 day period could be extended by 5 days if the Secretary of HHS determines extra time is required to institute an action against the food. Furthermore, the Secretary may require immediate recall of an article of food, if the Secretary has "reason to believe" that the food is adulterated. The distributor of the food subject to the recall order would have no opportunity for a hearing prior to the execution of the recall and could only challenge the action in a United States district court.

Civil penalties of up to \$250,000 can be imposed upon any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food violating the tolerance provisions of the FFDCFA, regardless of the significance of the potential health risk involved.

United believes that such additional FDA enforcement authorities are overly broad and unjustifiable from the perspective of risks from pesticide residues in foods.

Mr. Chairman this review does not capture fully the scope of our concerns related to the Administration's bill. Many other provisions including reduced risk pesticides, pesticide use record keeping and tolerance expiration cause us concern. The broad scope of the reforms contained in the Administration's bill are overwhelming and miss the need to focus attention on the most important issues: cancellation under FIFRA, minor use pesticides, a reasonable negligible risk standard in lieu of the Delaney clause and national uniformity of pesticide tolerances.

Despite the pressing need for reform we must oppose the Administration's legislation. The proposals represent a panoply of confused and overly prescriptive provisions without focus on the fundamental requirements for reform.

BEFORE THE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION OF THE
HOUSE COMMITTEE ON AGRICULTURE

HEARING ON FIFRA REFORM

STATEMENT OF THE MINOR CROP FARMER ALLIANCE

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Submitted: June 15, 1994

BEFORE THE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION OF THE
HOUSE COMMITTEE ON AGRICULTURE

HEARING ON FIFRA REFORM

STATEMENT OF THE MINOR CROP FARMER ALLIANCE

Mr. Chairman, my name is Christian Schlect and I am Chairman of the Minor Crop Farmer Alliance (MCFA or Alliance) which comprises 134 local, regional and national commodity organizations interested in solutions to the minor use issue. Accompanying me here today is Daniel Botts who is Chairman of the MCFA Technical Committee.

The Alliance, representing organizations that grow and market agricultural commodities, was formed in November 1991 to address legislative and administrative policies to ensure the continued availability of crop protection chemicals for minor use crops. Although the Alliance's focus is on addressing proposed changes to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the MCFA also addresses other issues to achieve its objectives. These include funding for agricultural research, harmonized international agricultural chemical standards, support for integrated pest management, and any needed reorganization of existing federal departments or agencies to make them more efficient in addressing crop protection issues.

On June 10, 1993, the Alliance testified before this Subcommittee and provided extensive background on the origins and suggested solutions to the minor use issue.

In summary, when we talk about the minor use pesticide issue, what is meant is the loss of crop protection tools, not for safety reasons but for economic reasons. Basically, the costs of generating data to satisfy the U.S. Environmental Protection Agency's (USEPA) requirements for either registering or re-registering crop protection tools for a particular use outweighs the return that the agricultural chemical manufacturer expects from the sale of that product. For example, if it costs \$100,000 to develop data to support a particular minor use pesticide and sales for that use are \$75,000, clearly there is an economic disincentive for the manufacturer to develop the required data. This problem applies to both obtaining

registrations for new uses and maintaining existing registrations. Over the past five years, this issue has become particularly acute.

ACCORDING TO THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE (NASDA), A MEMBER OF THE ALLIANCE, THE LACK OF SUFFICIENT MINOR CROP PESTICIDES HAS TWO ADDED IMPACTS. THE FIRST IMPACT IS ON STATE RESOURCES, IN THAT STATE PERSONNEL MUST BE DEVOTED TO THE DEVELOPMENT OF REQUESTS FOR SECTION 24c AND SECTION 18 EXEMPTIONS, MOST OF WHICH ARE IN RESPONSE TO MINOR CROP PEST CONTROL NEEDS.

THE SECOND IMPACT IS ON PESTICIDE INVESTIGATION AND ENFORCEMENT EFFORTS. STATES MUST PURSUE CASES OF LABEL VIOLATION WHERE THE PESTICIDE IS NOT REGISTERED ON THE CROP SUBJECT TO THE INVESTIGATION, BUT IS LABELED FOR USE ON SIMILAR CROPS. CIVIL PENALTIES ARE IMPOSED FOR VIOLATIONS SUCH AS THE APPLICATION OF RONILAN ON BLACKBERRIES, ALTHOUGH IT IS LABELED ON STRAWBERRIES AND RASPBERRIES, OR THE APPLICATION OF LOROX ON CELERY, WHICH IS LABELED FOR CELERY APPLICATION EAST OF THE ROCKY MOUNTAINS ONLY. THE END RESULT IS THAT CROPS ARE EMBARGOED AND CIVIL PENALTIES CAN BE LEVIED ALTHOUGH THE VIOLATION IS PRIMARILY TECHNICAL IN NATURE. IN MOST INSTANCES, ECONOMICS IS THE REASON WHY A PRODUCT IS NOT ON THE LABEL.

We would like to focus now on the legislative solutions to the minor use pesticide issue which we believe can and must be enacted this year.

House bill H.R. 967 by Congressman de la Garza, Roberts, Stenholm and Smith has 128 cosponsors. The companion Senate bill, S. 985 by Senators Inouye and Lugar has 43 cosponsors.

The Minor Crop Pesticides Act would essentially:

(1) Define minor uses to include those non-economic uses involved on commercial agricultural crops or sites, on animals, or for public health.

(2) It would extend exclusive data protection for 10 years when such data relate solely to a minor use pesticides. For instance, when a manufacturer registers a pesticide for the first time, EPA is required to maintain their data in confidence. Competitors can rely on those data only after a certain time period, i.e., after 10 years have elapsed, or if the original data submitter voluntarily allows them access. The legislation would provide additional protection for data relating to minor use pesticide information.

(3) The legislation would extend the time for submission of residue chemistry data for minor use pesticides for two years after the final deadline for submission of data for the major pesticide uses. Basically, this would establish two categories

of pesticide information, one for major uses and the other for the minor uses. The pesticide manufacturers have indicated that it would be beneficial if they would be allowed to complete the re-registration process by developing the data necessary to support their major uses first, and then subsequently supply the data necessary for supporting the remaining minor uses.

(4) The legislation would expedite minor use pesticide registration decisions in three instances: (1) if there are three or more minor pesticide uses per major use, (2) if the use would serve as a replacement for a use that has been cancelled within five years of the application, or (3) the use would avoid the re-issuance of an emergency exemption. I think that makes sound public sense. If the USEPA is going to cancel a particular chemical or if the USEPA, which has been under much criticism lately for continually issuing emergency exemptions for pesticide uses, can get uses addressing those circumstances registered, registration applications for those uses should receive a priority.

(5) The legislation would also authorize the conditional registration of minor pesticide uses that were previously cancelled or proposed for cancellation or deletion after December 24, 1988. Essentially this would return to the market for a period of time certain chemicals that were previously cancelled where a clear determination that no safety triggers were exceeded can be made.

(6) The legislation would also provide a temporary extension of unsupported minor pesticide uses to the final deadline for submission of data for uses being supported. This is a transition period provision. In other words, what is needed in the farmer community is early notice that a particular chemical is being eliminated. Manufacturers have a reason not to provide that notice. When pesticide manufacturers decide not defend a particular pesticide use, sometimes they wait until they submit their voluntary cancellation request to the agency prior to notifying user community of the loss of a use. There needs to be a better communication system, a warning system that identifies when a particular use is going to be lost at the earliest possible time.

(7) The legislation would also establish USEPA and USDA minor pesticide use programs. It is important that those two agencies cooperate. As strange as it sounds, in Washington, D.C. the USDA and USEPA may not always talk to one another. As a matter of fact, often they talk at one another, if they talk at all, and that has to change. This is not good for farmers or for the regulated community or any other parts of our society. Both federal entities have an opportunity to do great good or great harm. We would suggest that they focus on doing the greater good, and one way they're going to achieve that is by coordinating their efforts in the pesticide area.

(8) The legislation would also provide a matching fund for data development with industry and the USDA. If minor use data are required, under a matching program a grower organization, for example, could put up half the money with the government putting up the other half. The growers would then repay the government share over a longer period of time, e.g., 10 or 20 years.

(9) The Minor Crop Farmer Alliance also wants an increase in funding for the IR-4 program and have additional funds devoted to the IPM programs. We think these are very important.

(10) We would also support expedited treatment of biologicals and so-called reduced risk chemicals.

As a solution to the minor use issue, some have suggested simply increasing exemptions from data submission for a number of these minor uses. If EPA does not require so much data, the potential economic impact would be addressed. However, pesticide uses associated with fruits and vegetables are those that are in the public's mind. If a residue problem comes up, you normally don't hear about it in reference to Christmas trees. You hear about it developing on fruits, vegetables and specialty crop foods that people typically consume. The publicity is particularly intense if it involves children. The Alliance supports those actions necessary to protect the health and safety of our food supply and will work with the Administration to develop a comprehensive approach necessary to assure the consuming public of the safety products we grow.

The minor use provisions in the Administration's proposed pesticide/food safety reform legislation are a major step forward. We are encouraged by the Administration's recognition of the minor use problem by including many of the provisions of H.R. 967 and S. 985 in its proposed legislation.

We look forward to continued discussions with the Congress and the Administration regarding these provisions. It is imperative that reasonable changes in the process for minor uses be made this year.

Attached to our testimony is a revised chart comparing the Minor Crop Farmer Alliance (MCFA) proposals contained in HR 967 and S. 985 with the Administration's proposals contained in H.R. 4329 and S. 2050. Based upon a review of the Administration's proposals, the following comments are offered for your consideration:

1. Section 10 Minor Use of Pesticides (a) Definition, p. 74. The Agency has established criteria by which a pesticide use is automatically considered a minor use (a "bright line"). There are problems with the criteria. First it does not relate to use of a pesticide on a site, on an animal or for the protection of public health. Those uses would have to qualify under the second

part of the definition, namely that the use does not provide sufficient economic incentive for its maintenance. It is recommended that the criteria be revised to also create a "bright line" to address sites, animals and to protect the public health. Additionally, the farm gate value or potential return to the crop on an annual basis should be dropped from the definition. It simply is an unnecessary restriction. Further, the higher this value is in relation to the acreage of production, the greater the negative impact on the availability of crop protection tools due to liability concerns.

2. Sec. 10 Minor Use of Pesticides (a) Definition, p. 74.

The second part of the definition of a minor use is an economic definition i.e. the use does not provide sufficient economic incentive for its maintenance. However, the definition adds three additional criteria, any one of which must also be met namely, (a) there are insufficient efficacious alternative registered pesticides available for the use, (b) the alternatives to the pesticide pose greater risks to the environment or human health, or (c) the pesticide plays a significant part in managing pest resistance. It is recommended that these three criteria be eliminated. If a pesticide use is shown to be non-economic, it should qualify as a minor use. The minor use problem is an economic problem. It should not be saddled with additional unnecessary limiting criteria. For example, the criteria that there are insufficient efficacious alternative registered pesticide products available perpetuates making just one potential crop protection tool available for a minor use. Minor uses should not be limited to one pesticide. This can place the affected commodity at risk particularly if questions about that single pesticide ever arise jeopardizing the continued use of the pesticide.

If the criteria are to remain, another alternative criteria should be added, namely that the pesticide is included as part of an Integrated Pest management ("IPM") program.

3. Section 9 Reduced Risk Pesticides, (g) Use of Research Funds, p. 71. This provision would authorize use of grower funds for pesticide research and technology transfer plans. However an exclusion exists namely "[n]o monies under this section may be made available to persons directly or indirectly engaged in the registration of pesticides under this Act for profit." It is not clear what "directly or indirectly" mean. There may be grower associations or organizations which may register pesticides for profit as a small adjunct to the traditional non-profit activities of the organization. In any event, it is suggested that this sentence be amended to read "[n]o monies under this section may be made available to persons whose business substantially involves the sale of pesticides for profit." This should eliminate chemical companies which are the entities at which the provision is presumably aimed.

4. Section 10 Minor Use of Pesticides (b) Adequate Time For Submission of Minor Use Data, p. 75. The first sentence of subparagraph (n)(1) should be revised to indicate that the Administrator, on the request of a registrant "or at the request of a user with the consent of the registrant," may delay action to delete a minor food or feed use. This would provide user community greater direct involvement in the extension process.

In addition to the foregoing, consideration should be given to requesting Congress to modify the Administration's bill to add a number of provisions included in H.R. 967 and S. 985 which are not yet part of the Administration proposals. In particular, the proposed grant program and the establishment of minor use programs within both EPA and USDA should be included by the Congress.

In conclusion, Mr. Chairman, we believe that the differences between H.R. 967 and the minor use provisions of H.R. 4329, the Administration bill, quickly resolvable. We believe this issue can and should be resolved this year and we look forward to working with you and Chairman de la Garza to enact minor use legislation this year.

(Attachment follows:)

**OUTLINE OF MINOR CROP PESTICIDES ACT (MCFA)
WITH ADMINISTRATION PROPOSALS**

MCFA	ADMINISTRATION
1. Minor use defined and based on lack of economic incentive to maintain the use.	1. Minor use defined both as a "bright line" and as an economic problem. The "bright line" definition includes qualifiers i.e. To automatically be considered a minor use, the total acreage of the crop must be less than 300,000 acres and the average annual production value of the crop must be less than \$500,000,000. Another way to qualify as a minor use is to demonstrate that the use does not provide sufficient economic incentive to support the use. In addition, in such circumstance, one of three other criteria must be met i.e. (a) lack of efficacious alternatives, (b) alternatives pose greater risk to the environment or public health or (c) the pesticide has a significant role in managing pest resistance.
2. Minor use includes use on animals, commercial agricultural crop or site, or for public health.	2. Minor use includes use on a commercial agricultural crop, on an animal, or for the protection of public health.
3. Exclusive data use protection extended for 10 years if such data relate solely to a minor use. Includes new registrations and existing registrations.	3. Extend exclusive data use protection for two years for those pesticides for which the Administrator has approved at least three minor uses prior to the expiration of the original exclusive use period, i.e. within 10 years of the date the first use of the chemical was registered.
4. Extend time for submission of residue chemistry data for minor uses for 2 years after final deadline for submission of data for other uses.	4. Extend the time for development of residue chemistry data for minor uses until the last study date for the chemical.
5. Administrator may waive minor use data requirements in certain circumstances.	5. Not discussed. (Essentially in current regulations).

MCFA	ADMINISTRATION
6. Expedite minor use registration if active ingredient is to be registered solely for minor use or if there's 3 or more minor uses for every non minor use, use would serve as a replacement for any use that has been cancelled within 5 years of application or minor use would avoid re-issuance of an emergency exemption.	6. Prioritize pesticide applications as follows: (a) those that would replace the need to issue a § 18 emergency exemption (b) those that reduce risks for pesticides in a cancellation or suspension proceeding (c) reduced risk pesticides (d) minor use pesticides (e) other applications
7. Conditional registrations for minor uses shall be granted in certain circumstances.	7. Not directly discussed.
8. Administrator may conditionally register minor uses that were previously cancelled, proposed for cancellation or deleted after December 24, 1988.	8. Not discussed.
9. Temporary extension of unsupported minor uses to final deadline for submission of data for uses being supported.	9. Allow minor uses to continue until the due date of the final study required in the re-registration process.
10. Utilizing data for voluntarily cancelled chemicals.	10. Not discussed.
11. Establish EPA minor use program and USDA minor use program.	11. Not discussed. (USDA reorganization plan would include parts of the USDA minor use program).
12. Matching fund for data development with industry and USDA.	12. Not discussed.

STATEMENT OF JOSEPH PANETTA,
DIRECTOR OF REGULATORY AND ENVIRONMENTAL AFFAIRS,
MYCOGEN CORPORATION

ON BEHALF OF

THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

Thank you Mr. Chairman, and all the members of the Subcommittee, for inviting me to testify on EPA's proposal for reform of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and in particular, on Section 9 of the proposal, which addresses the registration of biologicals and reduced-risk pesticides.

I am Joe Panetta, Director of Regulatory and Environmental Affairs for Mycogen Corporation. I have been involved in the federal pesticide regulatory process for the last 15 years, first as a pesticide policy analyst with EPA, then as a product registration manager with a major chemical pesticide producer, and for the last five years with Mycogen Corporation. I have thus had the opportunity to view pesticide regulatory issues from various and diverse perspectives. At Mycogen, we are using biotechnology to increase food and fiber production by developing environmentally compatible biopesticides and improved, pest-resistant crops. Mycogen's highly selective biopesticides control target pests without leaving chemical residues in food, water or soil and without harming beneficial insects, wildlife or humans. A number of our products are available to farmers now. We are also in the process of applying for EPA registration of a new generation of genetically enhanced crop varieties that can resist damaging insects, tolerate new, low-toxicity herbicides, and produce larger, higher-quality yields. We had operating revenue of \$115 million in 1993. Based on a projected slight increase in revenue this year, we expect to be in the black for the first time in our 11-year history.

I am testifying today on behalf of the Biotechnology Industry Organization. BIO represents more than 500 companies, academic institutions, state biotechnology centers, and other organizations involved in the research and development of health care, agricultural and environmental biotechnology products.

Last September, the Clinton Administration announced a pesticide reform program aimed at reducing chemical pesticide usage and promoting the development of "reduced-risk" alternatives, including biopesticides. At the time this was announced, BIO member companies publicly commended the Administration for taking action in promoting the use of biologicals, an action we believe is long overdue. In fact, Mr. Chairman, both you and Chairman de la Garza have long shown foresight in the area of alternative pest control products, and have taken interest in ensuring continued registration of minor-use pesticides, a category that includes many biologicals and other reduced-risk pesticides. Last summer, in hearings you held on registration and reregistration, you heard a panel that included Mycogen's CEO, Jerry Caulder, testify on alternatives to traditional pesticide products. Your purpose in holding these hearings was identical to our purpose in producing our pest control products—to ensure that the American farmer has access to safe and effective pest management products as expeditiously as possible. We are not against the use of pesticides; in fact, one of our company's divisions provides custom pesticide application services in California's Salinas Valley. However, in a regulatory climate focused on reducing pesticide use, and

with public and media attention centered on the potential dangers of pesticides, it is important to ensure that farmers can address these concerns while continuing to produce wholesome and affordable food. As you said at last year's hearing, all new methods of pest control that add to the farmer's diminishing arsenal, and that promise safe and effective results, should be considered for use. I intend to focus my remarks here today on how the regulatory process will be improved in this regard under the Administration's legislative reform proposal.

BIO heartily endorses the EPA's intentions regarding biologicals and, separately, reduced-risk pesticides, as expressed in Section 9 of the proposal to amend FIFRA. Last year, in testimony given at your hearing on the registration process, biopesticides industry representatives stated that the regulatory process for biopesticides was simply not working, and that EPA needed to implement management changes to speed up the registration process and to dedicate specific resources to the review of biologicals. EPA has already moved forward to address these recommendations. Currently a new division is being formed within the Office of Pesticide Programs solely for the review and registration of biological pesticides. We believe that this first step will provide a significant, positive boost for the registration of these products, while avoiding conflicts of resources needed for the registration and reregistration of traditional chemicals. We believe that the following steps, which are the most significant to us of the many progressive changes proposed in Section 9, will ensure that the industry has greater incentive to develop reduced-risk and biological products and that they are made available to farmers more expeditiously.

- (1) *Criteria for the designation of reduced-risk pesticides* will be developed by EPA. While EPA issued a reduced-risk pesticide policy last year, it did not define the scope of products to be considered for reduced-risk status. Consequently, the responsibility was left to the applicant, who could not be certain whether a product would be accepted for reduced-risk consideration. This provision removes that uncertainty.
- (2) *Specific time frames for the review of reduced-risk pesticides.* This will remove some uncertainty from the regulatory process. Review times for acceptance of a product for reduced-risk consideration would be mandated, and actual review of the product would be completed within 180 days. The trade-off for this expedited review is immediate revocation of the registration if at a later time the product is shown not to meet the reduced-risk criteria. We believe that this is a fair trade-off, in view of the potential liability we would face in placing a product on the market that is later found to present a significant risk.
- (3) *Exclusive use for data extended by two years.* This provision requires the registration of at least three minor uses of the product during the exclusive use period. This section ensures both that applicants of these products are provided additional incentive for protection of relatively low-cost data

packages, as compared to traditional chemistry, and to some extent addresses concerns about the removal of older, minor-use products from the registration rolls.

- (4) *Conditional registration of biological pesticides.* Biological pesticides are typically of very low toxicity to humans, highly specific in their activity against target pests, and degrade quickly in the environment. Past experience with biologicals has shown that, due to their unique nature, they do not typically raise human health or environmental concerns. This section would allow our industry to move these products into the hands of farmers quickly, while we develop the data needed for registration, provided that the EPA can conclude on the basis of available data that the use of the product is in the public interest and that the product does not raise risk concerns. We believe that this procedure will place appropriately screened products into farmer's hands one to two years earlier than under current procedures.
- (5) *Integrated Pest Management (IPM).* Last year the Administration set a goal of increasing dramatically the number of farm acres upon which IPM practices are adopted. This Bill would provide for much-needed cooperation between USDA and EPA to provide information on IPM directly to farmers. IPM practices are applicable to all of the products that we produce, but of even greater significance is that many small producers of biological pesticides lack the field specialists needed to introduce farmers to these products. Mycogen and others are now taking a systems approach to pest control, in which IPM techniques are used to reduce chemical pesticide use and to protect against the development of pest resistance, while ensuring a high level of productivity. This provision would assist in providing this knowledge to farmers.

There are many other provisions of this section, including registration priorities, research into alternative pest control strategies, and coordination of efforts to register new products (in the face of pending regulatory actions that would affect the availability of older products), which we believe add substantially to Section 9's overall goal, which is to expedite registration of biologicals and other reduced-risk pesticides. We urge you to support the provisions of this section in your consideration of the Administration's overall proposal for amendment of FIFRA. If you should decide to move forward to address the issue of continued registration of minor-use pesticides, the provisions of Section 10 should be considered with the issue of minor use. Together, these sections form the basis of a strategy that Mycogen and BIO have advocated for several years.

In contrast to the last sixteen years, during which efforts to amend FIFRA have focused on special review and reregistration of old products, these sections look to the future. They provide for the registration, and hence the availability to farmers, of a new generation of products that are already being produced by large and small companies alike. Much progress has been made by EPA in the year since you last

*Statement of Joseph Panetta**June 15, 1994*

held hearings on this subject, for which the new management team in place in the Office of Prevention, Pesticides and Toxic Substances is to be highly commended. Our industry has obtained more registrations and Experimental Use Permits for biologicals and reduced-risk pesticides in the last six months than in any prior growing season, an accomplishment we attribute directly to this Administration's policy of supporting the introduction of these products. Farmers in turn have benefited, by having the opportunity to field-test such new products as a low-toxicity blossom thinner for apples and a higher-potency biological for control of caterpillar pests in cotton. The Administration's proposal brings to the registration process for reduced-risk products a degree of definition and certainty that has previously been lacking. Thus clarified, the process will move.

In conclusion, large and small companies, including Mycogen, have invested heavily in research and development to provide American farmers alternatives that are effective and safe for farm workers, for wildlife and for the environment. In the past, the EPA registration process has unnecessarily delayed the commercial availability of these products. At the same time, farmers have lost some of their most trusted pest control agents and have become increasingly alarmed about their production capabilities, especially for minor crops. Investors in small companies like Mycogen have started to become restless. The availability of joint-venture funds is drying up for industries that appear to be strangled by regulatory inefficiency. This Bill proposes some simple changes to the registration process for biologicals and reduced-risk pesticides that will certainly bring more of these desirable products to market. If Congress makes the commitment to expedited registration of these products, research and development will intensify and both old and new companies will provide farmers with much-needed, environmentally safer additions to their pest-control arsenals. Thank you.

James B. Boillot
National Agricultural Aviation Association

Mr. Chairman - Members of the Committee.

I am James B. Boillot, Executive Director of the National Agricultural Aviation Association. The National Agricultural Aviation Association has over twelve hundred members and represents the agricultural aviation industry nationwide.

We very much appreciate the opportunity to share our views regarding the Clinton Administration's proposed pesticide reform legislation.

Our review of the provisions contained in the proposal suggest that this legislation could have far reaching effects on agricultural aviation, but more importantly, on American agriculture and the consuming public.

May I explain the role and scope of Agricultural Aviation? The agricultural aviation industry is made up of small, independent businesses serving this nation's food and fiber production system. These businesses own and operate approximately 6,000 specially build airplanes and helicopters which are used to provide seed, fertilizer, and agricultural chemicals to this nation's fruit and vegetable, feed grains, fiber and forest producers. Simply stated, agricultural aviation enhances crop production, protects our forest resources, and controls health limiting pests and pathogens.

Our industry has changed dramatically since that day in 1921 when an airplane was first used to apply powdered lead arsenate to save a grove of Catalpa trees in Ohio, from an infestation of Catalpa Sphinx moths. Today, we use satellite positioning to guide our swath placement, specialized nozzles and spray products to minimize off-target deposition, and highly trained, professional pilots and staff to assure correct use and application. This industry operates under the regulatory oversight of not only the EPA and USDA, but also under the oversight of the FAA, DOT, the Fish and Wildlife Service, and state regulatory officials.

Mr. Chairman, we appreciate the interest which you and your colleagues are taking in this issue. As we study the provisions of this legislative proposal, we are concerned with the suggestion of a new philosophy that places no relevance on the benefits which can result from the use of pesticide products. Tremendous benefits, in the form of improved human health, efficiencies in food production, elimination of deadly pathogens, and the ability to farm without erosion producing tillage, have resulted from the use of agricultural chemicals.

We are all concerned with the safe use and application of chemicals and sincerely want to avoid unnecessary risk to any segment of our population or the environment. Currently, the Environmental Protection Agency (EPA) is able to weigh the real and demonstrable benefits of pesticide use in the production of a wholesome, abundant, and affordable food supply against known or theoretical

risks. We believe it is essential that recognition of the benefits that can result from the proper use of agricultural chemicals must be maintained as a factor in the determination of approval or disapproval of a specific product.

Another area of concern to agricultural aviators is the provision allowing citizen suit against those applying agricultural pesticides. There is substantial knowledge and training involved in developing the capability to correctly apply a chemical, or to determine if a product is being applied correctly. From our experience we know that there are people who become easily mistaken regarding what is happening in an application situation. The determination of compliance with correct usage and application requirements should remain as the sole purview of regulatory officials.

Mr. Chairman, this proposal contains language establishing as a goal, the reduction in the amount of pesticides that are used in production agricultural. To our knowledge, there is no scientific data suggesting that a product requiring ounces per acre provides more safety than a product requiring pounds per acre. We acknowledge that it may be politically expedient to state that pesticide usage has been reduced, but we suggest that it is far more appropriate to base registration and re-registration decisions on scientific data and to leave use decisions to those who have a clear understanding of the targeted pest and the conditions surrounding the specific application. We believe a goal of reducing the amount of crop protection chemicals can be counter productive and we urge the Congress to encourage philosophical goals of safe, economical, high quality food production, and care to assure that future generations have the same opportunity as we enjoy today. We believe this to be a realistic goal that can be accomplished when using the best scientific data to determine product approval and label instructions.

Mr. Chairman, we are also concerned with the language throughout the proposal suggesting that registration fees should be utilized to cover all manner of increased review and regulatory cost. The greatest beneficiaries of food production technology improvements are the American consumers and in the long run, they should pay for these increased fees. The American farmer is not in the position to pass these costs on and should not be asked to accept the burden of increased regulatory activity.

Mr. Chairman, we very much appreciate the desire of your Committee to determine what is best for all, the producer, the consumer, the environment, and future generations. We are grateful for the opportunity to comment and look forward to working with you to develop legislation that will guide the use of crop production chemicals and will assure the consumers of this nation a safe, high quality food supply, produced without damage to the environment.



Testimony Before the
Subcommittee on Department Operations and Nutrition

House Committee on Agriculture

Prepared by

Richard Wiles
Director, Agricultural Pollution Prevention

Susan Elderkin
Analyst

Environmental Working Group

June 15, 1994

Mr. Chairman, distinguished members of the Subcommittee. Thank you for the opportunity to testify today on pesticide reform legislation offered by the Clinton Administration.

I am Richard Wiles, director of agricultural pollution prevention at the Environmental Working Group, a non-profit environmental research organization here in Washington, DC.

In the past year, the scientific community has spoken with clarity and authority on the health risks associated with pesticides and the failure of the current regulatory system to protect public health, particularly the health of infants and children. The Clinton Administration has recognized the seriousness of the issue and has responded to these findings in the legislation we have before us today, HR 4329 and HR 4362. We will focus our comments today on HR 4362, which amends the Federal Food Drug and Cosmetic Act (FFDCA).

During the same period of time, the Environmental Working Group published two reports, *Pesticides in Children's Food* and *Washed, Peeled - Contaminated*, which together analyzed the results of over 23,000 pesticide residue analyses performed by the Food and Drug Administration (FDA), the Department of Agriculture (USDA), and the supermarket industry. *Pesticides in Children's Food* documented for the first time the prevalence of multiple pesticides in fruits and vegetables children eat most. It showed that it is not uncommon for children to consume individual pieces of fruit or vegetables with five or more pesticides on them. *Washed, Peeled--Contaminated*,

published in May 1994, confirmed these findings and revealed that normal consumer preparation of fresh fruits and vegetables does not remove or reduce the incidence of multiple pesticides present when the food is consumed.

These findings are particularly troubling since the Environmental Protection Agency (EPA) regulates pesticides as if people are exposed to them one at a time. Moreover, tolerances are based on the food consumption of a mythical average person in the population, a process that ignores the relatively high food consumption of young children when compared to adults. *Pesticides in Children's Food*, for example, found that up to 35 percent of lifetime exposure to some carcinogenic pesticides occurs by age five. The result of this heavy exposure early in life is that for the average child, the EPA's "acceptable" lifetime level of cancer risk from combined average exposure to eight pesticides is exceeded by age one.

These conclusions were supported and given toxicological context up by the National Academy of Sciences report, *Pesticides in the Diets of Infants and Children*. In essence, the Academy found the entire pesticide tolerance and regulatory system lacking and particularly inadequate in protecting young children. They concluded that "tolerances are not based primarily on health considerations" and that "the current regulatory system does not specifically consider infants and children." To address these problems, the committee recommended that "EPA modify its decision making process for setting tolerances so that it is based more on health considerations than on agricultural practices."

At the same time the committee made clear that children need special protection, and that "in the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children." They recommended that "the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete." They further cited the common occurrence of simultaneous exposures to different pesticides with the same toxic effect and recommended accounting for multiple exposures in regulatory risk assessments.

Since the release of these reports, a steady stream of new studies has been published further linking pesticides and their metabolites to human health effects, particularly cancers and other health effects mediated by the endocrine system (hormones). A hearing last October chaired by Congressman Waxman, emphasized the broad public health implications of widespread environmental contamination with pesticides that disrupt the human hormone system. At that hearing, the Environmental Working Group reported that 220 million pounds of 19 endocrine system disrupting pesticides

are applied each year to 68 crops, and multiple residues of these pesticides end up in the food supply. Scientific studies have emphasized that fetal or infant exposure to these pesticides can have serious effects on the reproductive system, and that these effects can manifest themselves throughout the life cycle from birth to maturity to adulthood.

We are pleased that the Clinton Administration has recognized and addressed these studies. We are also encouraged by the unprecedented cooperation between agencies. The Environmental Protection Agency, the Food and Drug Administration, and the Department of Agriculture have worked long and hard on this legislation, and we applaud their efforts at consensus.

The legislation before us today is vast improvement over the unacceptable proposals put forth by Representatives Lehman and Bliley in HR 1627, which is nothing but a thinly veiled attempt to weaken current law.

The Environmental Working Group supports the general public health orientation of the Administration's legislative proposals, particularly the proposal to end benefits considerations in tolerance setting. As the consensus position of the USDA, the FDA, and the EPA, this proposal to create a truly health based tolerance system is particularly laudable.

In general, however, the Clinton proposals, while well intentioned, fall short of the mark. This is particularly true in contrast to HR 4091, introduced by Congressmen Waxman, Synar, and Torres which provides an affirmative, scientifically sound alternative to the Delaney clause that increases public health protection, and which ensures protection of children from all pesticides.

The Administration Bill Sacrifices the Delaney Clause, Rather Than Refining It

The Administration proposes to remove pesticides from under the Delaney clause of the FFDCA and to compensate for this loss in public health protection with a discretionary health based standard, that is in theory designed to protect children. Unfortunately, as will be described below, this health standard is so riddled with loopholes that protection of infants and children is far from guaranteed. More critically, by effectively repealing the Delaney clause as it applies to pesticides, the Administration would eviscerate the only preventive environmental health standard in all federal law. The spirit of prevention embodied in Delaney would be lost, and nothing remotely equivalent would be substituted. More than any other provision of the Administration's package, this change is unacceptable.

In contrast, the Waxman bill, HR 4091, would refine the concept of prevention that is the essence of the Delaney clause, and replace it with a stronger, more rational phase-out requirement. Under HR 4091, pesticides classified as probable human carcinogens would be phased-out within five years of enactment. Within 6 months of enactment, the EPA would also be required to develop a list of pesticides that are potent reproductive or developmental toxins, endocrine disrupters, potent neurotoxins, as well as pesticides that are persistent or that bioaccumulate in living organisms. These pesticides would be phased-out within five years of such listing. All pesticides that remain in use would be required to meet a mandatory standard of safety specifically designed to protect infants and children.

This phase-out provision is an essential component of the Waxman bill. It begins to move farmers away from dependence on pesticides that are widely recognized as extremely hazardous, and it begins to deal with the multitude of residues and toxic chemicals that people encounter everyday, by reducing the burden of pesticides in the human environment. Most importantly, it accomplishes this objective in a reasonable, deliberate, scientifically defensible way, focusing on the most hazardous pesticides first.

The Administration's Safety Standard for Children is Discretionary

Protection of children must be mandatory, and standards in the law must not provide the EPA with discretion to set weaker standards for infants and children based on economic benefits to farmers or any other consideration. At the same time, federal law should not constrain science, nor prescribe specific risk assessment methods, and neither the Clinton nor the Waxman proposals do.

What the law should provide instead, is a firm and certain standard of protection for all children, regardless of the political orientation of subsequent EPA Administrators, or any other economic or political factor. The Waxman bill guarantees this protection, the Clinton proposal does not.

For example, both the Administration and Waxman language would set a single health-based standard for all pesticide residues in all foods. Both would require that pesticide residues in food pose "a reasonable certainty of no harm" to consumers defined as negligible risk. But the two packages differ in how this risk standard is described. For carcinogens, the Administration fails to define what negligible is. Although the EPA generally interprets negligible to mean that a pesticide should not pose a risk to consumers of greater than a one in one million increase in overall lifetime cancer risk, that standard is not written into HR 4362. The Waxman bill codifies this standard in law, guaranteeing uniform public health protection over time.

The Administration Bill Does Not Explicitly Protect Infants and Children From Carcinogens

The National Academy of Sciences states that young children may be at an increased risk from certain pesticides because their consumption and physiology differs from adults. This may be particularly true for carcinogens where lifelong exposure is thought to be responsible for the effect, and where exposures that occur early in life are likely to be more significant in producing the cancer due to the increased latency period, the higher exposure per unit of body weight, and the potential sensitivity of the infant or child to the physiological response that ultimately contributes to the cancer.

To protect children from heavy exposure to carcinogens early in life, the Waxman bill requires that exposure to cancer-causing pesticides not be disproportionately accumulated in the first five years of life. The Administration language includes no specific cancer risk standard to protect infants and children.

For Pesticides That Do Not Cause Cancer, The Administration's Bill Does Not Provide Children With Additional Safety Margins

Cancer, however, is a very crude measure of toxicity. Many non-carcinogenic pesticides present hazards to children that are as serious or more serious than cancer. For example, the fetus, infant and young child have very sensitive immune, nervous, and endocrine systems. Many pesticides are known to interfere with these sensitive systems in animals and in humans. Meanwhile, current standards for pesticides that cause these effects do not specifically protect children. Further, current study protocols for these effects, where they exist, do not require exposure of infant equivalent animals. In fact, the EPA has only recently begun to require studies for any but the most crude measures of these toxic endpoints.

This leaves children unprotected. In the absence of data relevant to children, The National Academy of Sciences recommended that up to a ten-fold safety factor be applied to all food tolerances. The Administration legislation proposes an additional ten-fold safety factor, but then allows it to be compromised solely at the Administrators discretion.

The Waxman bill, in contrast, requires the ten-fold safety factor, allowing for it to be eased only when complete and reliable data support a lesser standard.

The Administration Bill Does Not Protect Children From the Additive Effects of Pesticides

The NAS committee was clear that exposure to many different pesticides can cause additive effects and that children need extra protection from these combined effects. In fact, the NAS committee went so far as to devise an innovative new methodology to determine exposure and set standards that protect children from the combined effects of pesticides that cause the same toxic effect. The Committee further recommended that all routes of exposure to these pesticides be incorporated into food tolerance setting.

This latter concern has been addressed by both the Administration and Waxman proposals. The Administration bill, however, does not contain a requirement to protect children from the additive effects of pesticides that are either pharmacologically related or that have a common toxic mechanism or effect. The Waxman bill does.

The Waxman bill correctly shifts the burden of proof on this issue. It specifically requires that "if the Administrator identifies pesticides that are pharmacologically related or have a common toxic mechanism or effect, the Administrator shall treat such pesticides as having an additive deleterious action in the absence of evidence to the contrary." The Administration bill has no equivalent mandatory language and simply requires that the EPA examine all available information on the subject.

The Administration Bill Contains No Specific Data Requirements With Respect to Children

One recommendation of the NAS committee that is universally endorsed is the need for improved study protocols that will provide regulators with important information about the effects of pesticides on infants and children. This includes improving current protocols, such as cancer bioassays, to include dosing of fetal and infant animals, as well as new studies that examine the effects of pesticides on the immune, endocrine, and nervous systems during sensitive stages of development, throughout sexual maturity and on into old age.

The Administration bill contains no specific requirements for developing these new protocols or for testing pesticides to determine their potential health effects on infants and children. Although the EPA has begun some internal processes to develop new study designs, there is no requirement in the Administration's legislation that appropriate studies be developed or conducted. In contrast, HR 4091 requires EPA to establish testing protocols and data to determine whether exposure to a pesticide during fetal development, infancy, or childhood can cause serious adverse health effects.

Moving Towards A Health Based Standard

At its core, the Administration bill offers several basic changes in the way food tolerances are set for pesticides. None is more fundamental or commendable than their proposal to phase-out the consideration of economic benefits to farmers in the establishment of tolerances for pesticides in food. While the timetable for accomplishing this objective is too long - ten years - the proposal reflects the consensus view on the part of USDA, the FDA, and the EPA, that public health protection must supersede narrow economic interests.

Representative Waxman accurately characterized the situation in his statement accompanying the introduction of the Administration's bill when he said:

Pesticides are by far the most dangerous substances we intentionally add to foods, and they have never been subjected to the elementary public health standards that we demand of other food additives.

The time for this special treatment has ended. The Administration has recognized this, and has proposed to transform the regulation of pesticides in food into a purely health based system.

Summary

The Administration's proposed amendments to the FFDCA represent a reasonable starting point for discussion, with one important exception; the lack of any effective alternative to the Delaney clause.

The Administration's proposals address, however awkwardly, nearly all the issues relevant to the protection of infants and children. This prompts me to believe that the Administration's provisions could be strengthened to conform with the far more rigorous reforms offered by Representative Waxman. The Waxman alternative, HR 4091, provides tougher, more consistent protection for children, with the burdens of proof appropriately shifted to industry to prove that a pesticide is safe for children before it is allowed in, or allowed to remain in food.

However, the Clinton proposal to simply eliminate all preventive aspects of current pesticide law is plainly unacceptable from a public health perspective. While the Delaney clause can be made more consistent and scientifically rational, there is no improving on the core concept of Delaney, which is the prevention of exposure to the most hazardous pesticides in the food supply.

Testimony on Clinton Pesticide Reform Legislation
June 15, 1994

Page 8

Unfortunately, HR 4362, which could otherwise be characterized as a reasonable starting point for reform, is hamstrung by the absence of a sound, preventive, equally protective alternative to Delaney.

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**STATEMENT OF
MAUREEN KUWANO HINKLE
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NATIONAL AUDUBON SOCIETY
before the
SUBCOMMITTEE ON DEPARTMENT OF OPERATIONS AND
NUTRITION
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES
June 15, 1994**

Mr. Chairman and members of the Subcommittee, the National Audubon Society appreciates this opportunity to present testimony on the Administration's legislative package reforming the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA), HR 4329.

I am Maureen Kuwano Hinkle, and I have directed Audubon's agricultural policy program for over 13 years. We fully support and endorse the statement of the Environmental Working Group delivered today by Richard Wiles on the FFDCA part of HR 4329. We devote our testimony to the FIFRA part of the Administration's proposed amendments.

In general, we commend the Administration for an ambitious effort, unprecedented in its team approach to pesticides issues involving EPA, USDA, and FDA. The magnitude of, and the problems involved in, regulating pesticides prompted representatives of the three agencies to try to resolve deeply held differences and problems in regulation of pesticides. The need to change FIFRA and the FFDCA prompted this team effort. Geared to promote pesticides, the structure transferred to the new EPA in 1970 was inherently inefficient and inadequate to the task. In the 24 years since that transfer, regulation of pesticides has bogged down to such a degree no one is well served. The dysfunctional mechanism for regulating pesticides that EPA inherited continues to worsen each day.

Today, there is near universal agreement that change is necessary, and that Congress needs to provide the means to EPA to regulate more effectively. Of the proposals introduced to address change, HR 1627, the Food Quality Protection Act sponsored by Reps. Lehman and Bliley, would weaken and render even more ineffective the regulatory scheme. In contrast, the Administration's proposal, HR 4329 contains improvements over current law that would benefit all relevant parties. These improvements go to the heart of FIFRA and would substitute rulemaking for the cumbersome adjudicatory hearings, bring enforcement authorities up to the level of other

environmental laws, establish whistleblower protection, provide for citizen suits, and expand recordkeeping so that EPA and USDA can determine an accurate baseline of pesticide use. Such changes are absolutely necessary if there is to be order instead of chaos and predictability instead of chronic delays. Following are comments on specific parts of HR 4329.

Section 4 –Cancellation. Currently, adjudicatory hearings are so resource intensive, neither the agency nor individual companies can afford to participate. No company can afford the time, resources and expense of defending their product through the existing adjudicatory hearings. Yet HR 1627 would lengthen the current process which goes against every study of the agency's procedures in the past 24 years. The most recent recommendations calling for the adjudicatory law hearings to be replaced by informal rulemaking have come from the Administrative Conference of the United States (ACUS). ACUS studies the efficiency, adequacy and fairness of the administrative procedures used by federal agencies in carrying out administrative programs, and recommends improvements to the President, Congress, and the Judicial conference of the United States. The ACUS has made similar recommendations as far back as 1981 under President Reagan. Because ACUS is nonpartisan and is made up of lawyers and judges, their recommendations should hold special weight as you consider reforms to FIFRA. I have attached to this statement a copy of the recommendations, published in the February 1, 1994 Federal Register.

Section 9(a)(9)(A) – Regulations for Reduced Risk Pesticides. HR 4329 requires the agency to develop criteria for reduced use by rulemaking. The agency has sponsored three conferences on reduced use of pesticides, the third of which is being held June 13-15. Apparently the agency hopes that the third conference on reduced risk will give it the necessary wherewithal to produce criteria. To develop rulemaking in a timely way is simply unrealistic, given EPA's record on this issue. Even with guidelines in place since 1981 for biological pesticides (subpart M), the agency has failed to implement the regulations, despite the fact that they were greeted with unanimous praise from all parties. Those guidelines were developed by the American Institute of Biological Sciences (AIBS) for the agency. Three years ago, EPA Administrator Bill Reilly announced "imminent" policies regarding "safer" pesticides. The agency has been laboring over biological pesticides for 17 years.

Without legislative mandate, EPA prefers to take no action rather than make a mistake. Although the agency has moved rapidly in recent months to improve its record of registering "naturally occurring" products, this sudden haste could actually harm development of new alternatives. Naturally occurring products are not inherently safe or unsafe. Their toxicity and nontarget effects need to be evaluated according to their use, exposure and other characteristics in a deliberate procedure.

EPA's second reduced use workshop produced several recommendations that could be helped in legislation. They include building accountability into a fast track registration for safer products, generation of baseline data and the knowledge base needed to evaluate alternative pesticides, and creating incentives for researchers, pesticide producers and end users. All groups in the February workshop supported creation of a favorable environment for development of new technologies. Regulations can help enormously by specifying what kinds of products will receive not only quick review, but reduced requirements for registration.

Section 9(a)(9)(B) provides registrants the opportunity to designate a pesticide as a reduced risk pesticide. One can expect many applicants to take advantage of this invitation which puts the onus on the agency to figure out whether or not the product is in fact a reduced risk product. Audubon urges Congress to set forth criteria so that the registrant knows up front what regulatory door it can proceed through, what specific data waivers it is entitled to, and what procedures to expect.

Section 9(d)-- Conditional Registration for New Biologicals provides for conditional registration of a biological which is the same type of conditional that chemical pesticides receive. The registration is conditional for the duration of the conduct of required studies, that is, only for the period while studies are being carried out. A reduced risk registration should not have to undertake most of the lengthy studies that chemicals must undergo. While some "alternative" registrations will have to undergo the entire range of tests because their use is broadscale and nonspecific, an "alternative" product that is narrow and very specific, should not have to undertake the same tests. This difference is not recognized in HR 4329. As long as EPA treats conventional and new generation compounds the same, the agency is discouraging new registrations.

The major problem with uniform treatment of conditionals for chemicals and biologicals is that it perpetuates the *status quo* at the expense of technological advancement. While other countries are pushing ahead, the U.S. limits itself with existing technologies. If we are to be competitive in a world that is facing new and greater threats by pests and diseases, we must encourage innovative technologies and the body of knowledge that promotes them.

What are the threats? Rapid increase in resistance to pesticides frequently leading to emergency treatments; new and spreading non-indigenous pests from other countries; and the increased cost of clean up of pesticides that are detected above health advisories or acceptable levels.

Section 9(g)– Alternative Pest Control Strategies encourages research to reduce the incidence of pest resistance. Audubon is pleased that HR 4329 addresses pest resistance as a problem that needs attention. Resistance was a problem that concerned many workshop panels at the February 2-3, 1994 meetings. Audubon believe resistance deserves comprehensive attention. *Bacillus thuringiensis* (Bt) is being genetically engineered into most major crops, and is thus being projected to become a major part of the pest control market in the near future. With crop reports of resistance to Bt from Hawaii, Florida, New York and Japan, resistance management is no longer an isolated case or just an exception. The problem needs to be dealt with in an integrated, offensive approach.

Section 9(i) – Integrated Pest Management. Audubon is pleased that HR 4329 included the following mandate: "Federal agencies shall use integrated pest management techniques in carrying out pest management activities and shall promote integrated pest management through procurement, regulatory policies, and other activities." This incorporates the popular recommendation from the second reduced risk conference EPA sponsored in February 1994. Federal agencies manage large acreages of public lands, and utilize surplus stocks of pesticides on such lands. Their use has often led to environmental contamination not only on site, but on adjacent private lands. Leading by example is surely appropriate for pesticide use. Audubon would prefer that federal agencies utilize natural and biological control agents as a first resort, and chemical pesticides only as a last or emergency choice.

Section 12 – Use by Prescription. HR 4329 would allow use by prescription for restricted use pesticides in those states that develop "an appropriate state prescription use plan," or "establish criteria for issuing pesticide use prescriptions" along with authorization for persons "qualified under such criteria to issue prescriptions pursuant to the rule." Audubon has at various times suggested prescription use in order to tailor the need to the site-specific or situation-specific problem, minimize resistance, and limit use to actual need. A host of problems need to be addressed if prescription use is to be a viable option in the reduced risk section of this proposal. These include qualifications of the prescriber, liability, and conflict of interest, i.e., prescribing products in which the prescriber has a financial interest.

Section 16 – Pesticide Record Keeping. Audubon is pleased that record keeping would be expanded to include general use pesticides in HR 4329. There is a necessity to specify the kind of information that is required if any resulting surveys are to be meaningful. Actual pesticide use data is necessary to prove benefits of pesticides. Growers have a stake in the accuracy of pesticide use. If use of an important pesticide is not accurately reported, the benefits of that product will be underestimated, making it more likely that decisions on benefits will be undermined. Most importantly, researchers and regulators need actual pesticide use data to develop management strategies to

delay the onset of resistance *before the pesticides become ineffective against target pests.*

The kinds of information that Audubon believes are essential in addition to what is now required are: application rate per acre, number of acres, method of application, EPA registration number, target pests, crop or other site treated, and other practices employed.

Conclusion

Mr. Chairman and members of the subcommittee, we have not covered all parts of HR 4329. We appreciate the scarce number of days left in this legislative session, and the fact that nearly all members of the subcommittee have already signed on to HR 1627. Audubon sincerely believes that EPA needs to be made more effective if the industry is to survive in an increasingly complex and competitive world, and if the public is to be assured that safety is not being sacrificed in name of food production.

We do not demand a risk free world. We do not demand that carcinogens be removed from our food supply. Indeed, Rachel Carson herself claimed that synthetic cancer causing agents cannot be entirely removed from the modern world. What we do request is that the worst cancer-causing agents used on our food supply be phased out in an orderly predictable way. Companies will find the incentive to explore alternatives in the certainty that there will be a market for their product by a date certain. Other companies holding registrations of the "bad actors" can plan to phase down production in a predictable fashion and convert efforts towards new, needed alternative products.

HR 4329 is an important step forward, containing many essential ingredients for EPA to accomplish its tasks, but HR 4329 needs to be strengthened. As stated, the ACUS recommendations are attached, which contain several changes that are needed to effect adequate regulation. Any amendments to FIFRA should carefully weigh and incorporate these well argued changes in procedures for regulation of pesticides.

Our comments are aimed at trying to help the EPA regulatory framework to be more consistent, effective and workable. As bad as the current framework is, to destroy it with bad legislation would provoke a firestorm of protests across the country. We urge the subcommittee not to take that route.

(Attachment follows:)



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

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OFFICE OF
THE CLERK**Recommendation 93-5****Procedures for Regulation of Pesticides***Adopted December 10, 1993*

The Environmental Protection Agency cannot accomplish its substantive mission in regulating pesticides without change and improvement in the Agency's regulatory procedures. The Conference recommends the adoption of a more coordinated and strategic procedural framework for the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). EPA needs procedures that create multiple and reinforcing incentives for regulatory compliance by registrants, for timely and accurate decisionmaking by EPA, and for effective public participation.

The Reregistration Process

The reregistration of existing pesticides under contemporary risk assessment standards, and the removal of unacceptable pesticides from the marketplace, are examples where procedures can hinder the agency's prospects for success in its substantive mission. Reregistration of existing pesticides, which Congress originally directed to be completed by 1976, became sufficiently delayed so that Congress in 1988 amended FIFRA specifically to force the completion of reregistration by 1998. Yet subsequent delays in the reregistration process may cause EPA to miss this congressional deadline. To some extent, the delay may reflect the underlying difficulty and resource-intensiveness of the risk assessment enterprise with which EPA has been charged. There are some 50,000 pesticide products that are separately formulated from 642 identified active ingredients. Although EPA has tried to expedite its task by focusing reregistration on some 402 "cases" (composed of single or related active ingredients), each case can require evaluation of 100-150 separate studies, every one of which may pose further questions of scientific protocol and interpretation. It may be that EPA's Office of Pesticide Programs needs more personnel to match its regulatory task.

Whatever the case for additional resources (a question not addressed by the Conference), there is a more basic need for timely and adequate data from registrants--all else in the reregistration process depends on this. Yet the reregistration process does not now provide sufficient procedural incentives to encourage submission of timely and adequate data. In general, because registrants continue to market their products during reregistration, they have little to lose by regulatory decisions that are reached later rather than sooner. Although the 1988 FIFRA Amendments require registrants to identify data gaps, and commit to fill them, the 1988 Amendments do not provide the agency with sufficient tools to police tardy or inadequate data submissions.

As to tardiness, the 1988 Amendments authorized the agency to suspend registrations of those registrants that fail to submit data. But EPA must first provide nonsubmitters with 30-days' notice in response to which registrants can demand a limited hearing (which must be held within 75 days); the 1988

Amendments further provide that registrants suspended for not submitting data can have their registrations "reinstated" upon submission of the data. Some registrants, ironically, have used these suspension procedures as a means of obtaining penalty-free and self-awarded extensions of time. In the 7 months between August 1991 and February 1992, for example, EPA found it necessary to issue 70 Notices of Intent to Suspend for nonsubmittal of data, yet in the majority of these instances (53) the registrants merely submitted their data prior to exhausting their procedural rights and were no worse off for having missed their deadlines. To create an additional disincentive for untimely data submissions it is necessary to make lateness costly to the registrant. To this end, the Conference recommends that Congress authorize EPA to impose civil money penalties for untimely data.

As to the adequacy of data, EPA may now have the theoretical (but untested in court) capacity to suspend or cancel the registration of those pesticides for which inadequate data have been submitted. However, the more common response to inadequate data is a "data call-in," through which the agency demands that studies be redone—a source of additional delay that the agency has identified as significant. Even with respect to its highest priority pesticides, EPA has in the recent past found 50 percent of studies to be either inadequate, "upgradable" or otherwise requiring supplementation. Although the cost of redoing studies should provide some incentive for registrants to ensure that their studies meet EPA's quality criteria, it does not seem to provide a sufficient incentive. In fairness to some registrants, there is evidence that EPA itself may be partially to blame for the high rates of data rejection. In 1992, an internal agency review found that misinterpretation of data requirements and poor guidance from EPA case managers were in part responsible for the inadequacy of data submissions. The Conference therefore recommends that EPA promulgate and communicate clear data standards and guidance on the data expected from registrants. To help prevent the submission of inadequate data even after sufficiently clear agency guidance has been given, the Conference recommends that Congress authorize EPA to levy administrative civil money penalties upon registrants submitting data that fail to meet previously announced standards. This will not only create incentives for registrants to take the extra steps necessary to ensure the adequacy of their submittals, but it will also create incentives for the agency to make clear its expectations.

Whatever the additional tactical advantages that the agency may gain by improving its own ability to enforce data timeliness and adequacy, the sheer number of studies and the innumerable decisions requiring agency discretion suggest that more global incentives are needed to ensure that registrants themselves have a stake in timely and adequate data. The danger is that the reregistration process now has become, even with the best of intentions, an analytical treadmill powered by the rhythms of data call-ins, subsequent requests for data waivers and time extensions, submission of data that do not always meet EPA's standards for adequacy, and further data call-ins that restart the sequence. The Conference believes that the unique demands of the reregistration process justify congressional consideration of a "hammer" provision that would legislatively impose an automatic suspension of all "List A" pesticides (those high-priority pesticides to which there is greatest human exposure) for which there are still significant data gaps within the registrant's control, and of which the registrant is aware—subject to a provision for a registrant to petition for reinstatement. Such a provision would not only provide an overarching incentive for registrants to favor the completion rather than postponement of their data obligations, but it would also better align the reregistration process with FIFRA's central procedural presumption—that, in the face of uncertainty, applicants (especially those seeking to reregister pesticides with extensive human exposure) should bear the burden of proof in establishing that their pesticides do not pose unreasonable risks.

Suspension and Cancellation Hearings

Apart from improvements in the reregistration process, the Conference urges Congress to substitute a relatively informal decisionmaking process for the formal adjudicatory hearings that registrants can now demand in cancellation and suspension matters. In the past, formal hearings under FIFRA have averaged 1,000 days to complete. These hearings can directly impose on EPA significant resource costs and can also indirectly discourage the agency from aggressive prehearing negotiations with registrants (lest the registrant "take EPA to hearing"). It is not surprising that EPA has long sought alternatives to cancellation hearings. For years, it sought to identify problem pesticides for heightened regulatory

attention in a "Special Review" process. There is little need for procedural formality in these types of decisions. At issue in most cancellation and suspension proceedings are scientific data concerning risks and benefits, disputes over which can generally be well-ventilated when EPA gives registrants detailed reasons for the agency's actions and then provides registrants with sufficient time to file responsive written comments and supporting documentation. For those cases where oral testimony or cross-examination is justified, the benefits of more formal procedures can be preserved by providing registrants an opportunity to show cause why such procedures are warranted. Accordingly, the Conference recommends that Congress pattern cancellation and suspension proceedings on a basic notice-and-comment model, with more formal procedures available only if a party will be demonstrably prejudiced by the informal procedure.

Labeling and Phase-down Procedures

Although the reregistration process and adjudicatory hearings are the most visible aspects of pesticide regulation in need of procedural improvement, they are not the only places where procedural reform is important. Since the late 1980's, EPA has in fact sought to reduce the risks of pesticides through private negotiations with registrants over label changes that impose restrictions on use. Such regulatory action has the potential to attain interim risk-reduction quickly when warranted by available data, without going through the cumbersome Special Review and cancellation procedures, even when complete reregistration may still be years away. But there are also disadvantages to relying so heavily on private negotiations with registrants—chief among them the lack of participation among the various interested publics in crafting label changes. In the early 1980's, similar concern about privately negotiated Special Review and pre-Special-Review decisions seriously undermined the agency's credibility and slowed regulatory progress. In 1985, EPA adopted procedures to open the door for information from, and participation by, the public in those processes.¹ The Conference recommends that EPA adopt analogous procedures to regularize and open the agency's negotiated label program. In addition, because label changes are effective in reducing risk only if they are actually implemented in the field, the Conference recommends procedures to facilitate feedback from registrants, pesticide users, and all other interested persons on the effectiveness or ineffectiveness of the interim risk-reduction measures EPA has adopted. Moreover, the Conference recommends that EPA's Office Of Pesticide Programs (OPP) establish regular channels of communication with EPA's Office of Enforcement and Compliance Assurance to inform that office of all label changes and of any material information received by OPP on noncompliance with such changes.

The Conference also urges Congress to consider providing EPA with a new procedural device designed to accommodate a safer pesticides policy: the ability by informal procedures to order the phase-down of existing pesticides when there are available for use safer, effective pest management products or practices.² Empowering the agency to develop an informal phase-down mechanism would have several procedural advantages. First, ordering the phase down of an existing pesticide on relative risk grounds will cause less stigmatization of an existing product than would a cancellation proceeding based on the traditional, more absolutist "unreasonable risk" judgment. Second, phase-down procedures provide for an incremental style of decisionmaking in which EPA's reasoned judgments about comparative risk can be tested and reevaluated without making irreversible decisions about existing pesticides in cancellation proceedings. Finally, phase-down procedures based on relative risk can reinforce and integrate EPA's pesticide programs under FIFRA with other federal environmental programs.

¹40 CFR Part 154, Subpart B.

²Without taking any position on the substantive questions involved in determining the relative safety and effectiveness of pest control measures, the Conference notes EPA's interest in both the present and prior presidential administrations in developing such a substantive capability.

RECOMMENDATION

I. Adequacy and Timeliness of Data

A. EPA should adopt, whenever possible, rules setting clear standards for pesticide reregistration data and should communicate those standards to registrants.

B. Congress should authorize EPA to impose administrative civil money penalties on registrants for the failure to submit data by any applicable deadline, or for submitting data (even if timely) that do not comply with the data standards adopted by EPA.³

C. Congress should consider imposing an automatic suspension of "List A" (high priority) pesticides for which there still remain, by a date to be set by Congress, previously identified and significant gaps in data within the registrant's control, and of which the registrant is on notice. Once suspended, pesticides could be reinstated through a petition process.

II. Informal Procedures

A. Congress should eliminate the provisions in FIFRA allowing for formal adjudicatory hearings in proposed suspension or cancellation actions and should provide instead an informal procedure, including notice in the Federal Register, that informs registrants and others of the specific grounds on which EPA bases its proposed action and that provides a reasonable opportunity to file written comments and data. Only if a party will be demonstrably prejudiced by the written notice-and-comment process should the agency be required to grant the right to introduce oral testimony or to subpoena and cross-examine witnesses.

B. Congress should consider providing EPA the authority to order a phase down in the use of any registered pesticide through an informal notice-and-comment procedure in which EPA considers such factors as the relative risks and benefits of the pesticide at issue when compared with alternative pest management products and practices.

III. Public Participation

A. EPA should regularize and open for broader public participation its informal procedures for achieving interim risk reduction through pesticide label changes. EPA should inform the public, through a Federal Register notice, when it commences private label negotiations with registrants. EPA should simultaneously open a public "negotiation docket" into which interested persons may submit comments they believe might be relevant, for consideration by EPA and the registrants during their negotiations. If, after negotiations with registrants, EPA proposes a label change, it should publish a notice of the proposed change in the Federal Register and provide the public an opportunity to file written comments. The notice should include a concise, general statement of the proposed label's basis and purpose, including a summary of the material aspects of the agency's negotiations with registrants.

B. After requiring a label change, EPA should establish and publicize the availability of a "compliance docket," for any input about the effectiveness or ineffectiveness of interim risk-reduction measures. In addition, EPA's Office of Pesticide Programs (OPP) should communicate to EPA's Office of Enforcement and Compliance Assurance the adoption by OPP of label changes and any material information received by OPP in its compliance docket.

³Imposition of penalties should be through formal adjudication. See Conference Recommendation 93-I "Use of APA Formal Procedures in Civil Money Penalty Proceedings," 1 CFR §305.93-1.

STATEMENT
ON BEHALF OF

AGRICULTURAL RESOURCES CENTER (NC)
ARIZONA TOXICS INFORMATION
BRING URBAN RECYCLING TO NASHVILLE TODAY (TN)
COLORADO PESTICIDE NETWORK
COMMUNITY ALLIANCE WITH FAMILY FARMERS (CA)
COMMUNITY NUTRITION INSTITUTE
ENVIRONMENTAL HEALTH COALITION (CA)
GREENPEACE
INTERNATIONAL ALLIANCE FOR SUSTAINABLE AGRICULTURE
FARMWORKER JUSTICE FUND
FRIENDS OF THE EARTH
KANSANS FOR SAFE PEST CONTROL
KANSAS NATURAL RESOURCE COUNCIL
LOUISIANA ENVIRONMENTAL ACTION NETWORK
MANASOTA-88 (FL)
NEW JERSEY ENVIRONMENTAL FEDERATION
NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES
NEW YORK COALITION FOR ALTERNATIVES TO PESTICIDES
NORTHWEST COALITION FOR ALTERNATIVES TO PESTICIDES
PARENTS FOR PESTICIDE ALTERNATIVES (GA)
PESTICIDE ACTION NETWORK NORTH AMERICA REGIONAL CENTER
PESTICIDE WATCH (CA)
RACHEL CARSON COUNCIL
SIERRA CLUB
WASHINGTON TOXICS COALITION

BY
JAY FELDMAN, EXECUTIVE DIRECTOR
NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, D.C.

JUNE 15, 1994

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to testify before the Subcommittee on the critical topic of pesticide policy reform. I am Jay Feldman, executive director of the National Coalition Against the Misuse of Pesticides. I am testifying today on behalf of 25 international, national, statewide and regional environmental, consumer, farm and labor organizations that are working to promote a *meaningful* pesticide reform and sustainable pest management agenda. These groups work in

communities on a day-to-day basis against the backdrop of poor federal and state policies that allow pesticide contamination and poisoning and offer limited incentives and assistance for the adoption of alternative pest management strategies. Our special vantage point brings a unique and important perspective to our evaluation of reform proposals now before Congress.

As the members of this Subcommittee know all too well, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) bring with them controversial debate and polarization, as a result of perceived differences and wide schisms between positions among the affected groups and people in the pesticide industry, pesticide user groups, and the public interest community, including the environmental, consumer and labor. While the historic controversy and differences among these groups has led to a high degree of frustration among policy makers and others, the history also includes, amidst the controversy, the passage of amendments to FIFRA in 1988 that reflected the adoption of language that "everybody could live with," language which met basic public health and environmental requirements at the time. There was, in 1988, general recognition in this Subcommittee of the urgent need to get the pesticide reregistration program moving ahead, and eliminate a major impediment to regulatory action in the form of a costly indemnification program for banned pesticides.¹ Today, we expect to see in Congress increasing recognition of the urgent need to act in two ways: (i) ensure the orderly removal from the market of pesticides that cause identified adverse human health or environmental effects, including but not limited to cancer, endocrine and reproductive effects, the highest category of acute effects, bioaccumulation and persistence; and, (ii) provide direction and support for economically and biologically viable pest management alternatives that do not rely on chemically-dependent control strategies.

There are important analogies today to events in 1988, as this Subcommittee and Congress begin the important work of developing a meaningful policy response to the call for reform. As in 1988, today the public wants Congress to act on safety questions associated with pesticide use. Food safety is of critical concern and protection of children is uppermost in people's minds. The public wants both improved protection and the adoption of alternative pest management approaches that are not dependent on toxic solutions when non-toxic approaches can get the job done. Studies continue to confirm adverse health effects associated with pesticide exposure.

¹Unfortunately, reregistration delays continue to plague EPA, calling for Congress to revisit this problem. See GAO, *Lawn Care Pesticides: Reregistration Falls Further Behind and Exposure Effects are Uncertain*, April 1993, GAO/RCED-93-80. This report indicates that EPA's reregistration program is behind schedule, in some cases by as much as four years. The report also highlights EPA review practices which may undermine the quality of decisions. See also GAO, *Pesticides: Pesticide Reregistration May Not Be Completed Until 2006*, May, 1993, GAO/RCED-93-94.

While there are these important similarities to the controversial debate and resolution in 1988, there are also some important differences today. First, an increasing number of farmers have shown an openness to options that move their operations away from dependence on pesticides. Farmers themselves are asking for alternatives to toxic chemicals, realizing that there are serious health risks and that continued pollution of their soil and water will only diminish the value of their land and their legacy. Second, environmental and health advocates leading the charge for improved pesticide restrictions, are also working with farmers and farm groups and exhibit a growing understanding of farmers needs for productive and profitable farming operations. With these two critical differences, we have an opportunity to discuss increased pesticide restrictions and the adoption of alternatives with a greater spirit of optimism than many have had in the past.

It is our belief that the public's desire for increased protections² can be met with a minimum of short-term economic dislocation, and with sensitivity toward those who are currently dependent on toxic solutions. Our goal is to effect a transition away from pesticide dependency that results in long-term sustainability and offers new economic opportunities, not pull the rug out from under those who have not yet developed the foundation of alternative practices.

According to the U.S. General Accounting Office (GAO), "Pesticide use has doubled since the publication of *Silent Spring*, increasing from 500 million pounds per year in 1964 to over 1 billion pounds in 1989,"³ excluding wood preservatives, disinfectants and sulfur, which account for another billion pounds.⁴ However, the health and environmental effects data has not kept pace. There are no EPA registration or reregistration testing requirements for endocrine and immune system effects and neurotoxicity testing is inadequate. Monitoring for pesticide incidents has been neglected during the past decade

²Patricia McGrath Morris et al., *What Americans Think About Agrichemicals*, Public Voice for Food and Health Policy, April, 1993. A nationally representative 800 person sample, conducted by Fingerhut/Granados Opinion Research Co., found that 92% of Americans expressed concern about the health problems caused by chemicals and pesticides used to grow food, including 60% who are very concerned and 32% who are somewhat concerned; 68% are very concerned about the effect on young children and 24% are somewhat concerned. These results confirm earlier polls conducted by the Food Marketing Institute. A Harris Poll taken in late 1988 found that 84 percent of those polled would like access to food grown without pesticides.

³Peter F. Guerrero, *Pesticides: 30 Years Since Silent Spring --Many Long-standing Concerns Remain*, GAO, July 23, 1992, GAO/T-RCED-92-77.

⁴Arnold L. Aspelin et al., *Pesticides Industry Sales and Usage, 1990 and 1991 Market Estimates*, Economic Analysis Branch, Office of Pesticide Program, EPA, Fall, 1992.

by EPA, crippling EPA's ability to investigate and detect pesticide problems. EPA's failure to fully test and disclose so-called "inert" ingredients in pesticides adds yet another unknown factor into the toxic mix.

Principles for change

Any proposal for pesticide policy change or reform must be measured against a set of principles that serve as the minimal national standard of public health and environmental protection. As GAO said in a May, 1994 report, "Because scientific data are not always adequate to quantify risks and benefits, the choice of an appropriate regulatory standard entails value judgments and is, ultimately a policy decision."⁵ Furthermore, we believe it is an abuse of science to suggest that it is possible to draw a bright line standard of protection given the incomplete and inadequate data currently available on a range of critical issues, including but not limited to sensitive population groups, multiple exposure to pesticides, and threshold chemical effect levels. Moreover, since no limits are imposed on the volume of pesticide production, we cannot accurately calculate actual human and environmental exposure. For all these reasons, public policy should embody efforts aimed at prevention of adverse health effects and pollution prevention.

In order to reduce damage to human health and the environment from the serious, unnecessary and unacceptable adverse effects of pesticides, and to provide a sound basis for sustainable development of our communities, we advocate a shift from reactive chemical methods of pest control to preventive methods that incorporate pest management as a component of bio-integrated resource systems management. We seek protection for humans, other non-target organisms and the environment from the effects of pesticides in their manufacture, transport, use, and disposal --that is, from cradle to grave. To achieve this goal, we call for the adoption of policies that are based in public health principles that prevent health damage and establish economically and biologically viable pest management alternatives to current chemically-dependent control strategies. We support reducing the reliance on pesticide use in agricultural and nonagricultural settings as the key to environmental pollution prevention.

Consequently, we support full implementation of the preventive health policy principle now embodied in part in the Delaney Clause of the Federal Food, Drug and Cosmetic Act, which prohibits the introduction of cancer causing pesticides into processed food. Conversely, we oppose approaches to pest management that condone continued use of and exposure to toxic pesticides based on so-called negligible risk standards because they are scientifically and ethically indefensible. We advocate instead legislative and regulatory actions to extend the Delaney principle to include prohibitions against residues in raw as well as processed foods and against pesticides that

⁵U.S. General Accounting Office, *Pesticides: Options to Achieve a Single Regulatory Standard*, GAO/RCED-94-57, May, 1994.

persist and bioaccumulate and cause other adverse effects besides cancer, including, for example, reproductive and developmental disease, immunological dysfunction, endocrine disorders and acute toxicity. In addition, we advocate for nonagricultural pesticides to be subject to the same regulatory provisions as agricultural pesticides and a parallel extension of the preventive health policy principle to nonagricultural pesticide usage.

The transition to environmentally sound pest management will require enforceable interim measures including: 1) phase-out of toxic pesticides; 2) public disclosure of pesticides known to cause adverse effects until phaseouts are implemented; 3) exposure and residue standards to prevent adverse effects to the most susceptible human populations, including children, the elderly, the chemically sensitive, and highly exposed groups, such as farmworkers⁶; 4) minimization of ecological damage due to pesticide use; 5) measurable and enforceable pesticide use reduction goals, as well as incentive-based use reduction; 6) economic incentives and technology transfer programs that ensure pest managers have the necessary tools to achieve reduction goals; and, (7) retraining and assistance programs for production workers displaced by conversion to sustainable systems.

Below we outline the following principles by which reform proposals should be measured:

1. **Enforceable phaseouts of toxic pesticides, including those that are:**
 - toxicity category 1 acutely toxic
 - carcinogenic
 - endocrine disruptors
 - reproductive toxins
 - developmental toxins
 - neurotoxic
 - immunotoxic
 - persistent
 - bioaccumulative
 - groundwater contaminants
2. **Point of purchase public disclosure of the use of pesticides known to cause adverse effects, until phaseouts are implemented.**
3. **Measurable and enforceable use reduction goals and programs for publicly funded pesticide users.**
4. **Voluntary, incentive-based use reduction in agriculture and non-publicly funded uses.**

⁶Included here is the need to act on environmental justice principles and improve protections for those who are disproportionately hurt by toxic pesticide exposure.

5. Full pesticide use reporting, and full public disclosure of the data.
6. Protection of most susceptible and otherwise vulnerable populations.
7. A prohibition against the export of pesticides that are banned, severely restricted or never registered. Where pesticides continue to be exported, mount efforts to ensure development of stringent, domestic regulatory enforcement mechanisms and programs to promote nonchemical pest management in importing countries.
8. Effective retraining and other assistance programs for displaced pesticide production workers.
9. Protection of state and local authority to regulate pesticides more stringently than the federal government.

Whether we are talking about the Clinton Administration's proposal contained in *FIFRA Act Amendments of 1994*, H.R. 4329, and *The Pesticide Reform Act of 1994*, H.R. 4362, *The Food Quality Protection Act*, H.R. 1627 (Reps. Lehman and Bliley), or the *Pesticide Food Safety Act of 1994*, H.R. 4091 (Rep. Henry Waxman), we must evaluate proposals against the only meaningful yardstick: Will the measures ensure that we are removing hazardous materials from the market while effecting a transition to alternative approaches?

Many environmental groups have previously testified before this Subcommittee on H.R. 1627 in strong opposition to this legislation because it does not offer the level of human health and environmental protection that the public wants. The legislation adopts the notion that pesticides are too stringently regulated, despite the findings of numerous studies that have found the need for a greater degree of protection. For instance, the *Pesticides in the Diets of Infants and Children*, released by the National Academy of Sciences in June, 1993, concluded, "The federal government should change some of its scientific and regulatory procedures to afford infants and children greater protection from possible adverse health effects of pesticides in their diets. . .[and] advises the government to consider all sources of exposure --dietary and non-dietary when assessing risks to children's growth and development."

The Clinton Administration's Pesticide Proposal

The Clinton proposal fails on the central and critical issue of public health protection and preventive health policy as related to a series of adverse health and environmental effects, including cancer, endocrine system effects, acute neurotoxicity, bioaccumulation and persistence. In an effort to find a single standard of protection across Section 408 and 409, FFDCA, the proposal errs on the side of a weak uniform standard of protection by embracing a "negligible risk" standard. The supposedly bright line that the Clinton Administration characterizes as a "reasonable certainty of no harm" is actually a blurred territory characterized by false exposure assumptions and

uncertainties and a series of unknown factors.⁷ At the same time, the proposal fails with respect to providing a systematic and effective framework for pesticide use reduction that will ensure movement away from pesticide dependent pest control systems.

In June, 1993, many national environmental, consumer and labor groups adopted a position that clearly states the need to remove carcinogens from use.⁸ The groups took this position because of the problems associated with risk assessment. Among other groups, the Natural Resources Defense Council articulated at that time why a phase-out is essential.

Why a Phase-Out is Needed. Quantitative risk assessment remains part art, part science. There are numerous areas of uncertainty involved in developing an estimate of the risk potentially posed by a pesticide residue or by any other environmental pollutant. Uncertainties derive from a broad array of problems, including gaps or uncertainties in toxicological data, our failure to understand the differences between the effects of a chemical on laboratory animals versus humans, problems in determining what subpopulations such as children are at special risk, difficulties in translating from high dose to low dose exposures, the lack of hard data on actual exposures to the chemical from multiple sources, and many other problems.

When these uncertainties arise, the risk assessor seeks to make reasonable assumptions about the missing data, and plugs [in] those values, and sometimes "safety factors" intended to try to compensate for possible underestimation of risks, in reaching the final risk estimates. However, the uncertainties in risk estimates can be large (orders of magnitude) when the data gaps are significant. Moreover, for some data gaps—such as the lack of information on interactive effects of multiple

⁷Rep. Waxman's H.R. 4091 is the only proposal before Congress that embraces the prevention principle of the Delaney Clause, that risk assessment is inappropriate for certain adverse effects and requires their phase-out. The bill has gained the support of numerous public interest groups expressly because of its uniform phase-out of known and probable human carcinogens. Its provisions allow for the continued use of possible human carcinogens with full disclosure to the public.

⁸*Pesticide Reform Agenda: An Agenda for Reform of the Nation's Pesticide Laws*, June 21, 1993. Endorsed by AFL-CIO, Center for Resource Economics, Citizen Action, Consumers Union, Farmworker Justice Fund, Friends of the Earth, Government Accountability Project, National Audubon Society, National Coalition Against the Misuse of Pesticides, Natural Resources Defense Council, Physicians for Social Responsibility, Public Voice for Food and Health Policy, Sierra Club, and World Wildlife Fund. The document reads, "Ultimately, as in the case of CFCs, methyl bromide, and other ozone depleters, there should be a phase out of food tolerances for carcinogenic pesticides over the next five to seven years."

carcinogens consumed in the real world—risk assessment traditionally cannot consider these problems. As the National Academy of Sciences has made clear, in many ways standard risk assessments may seriously underestimate risks, particularly for infants and children.⁹

While the value of the legislative package is undermined by the very health and safety standard on which it is built, there are other elements that should be improved, as well. The legislation's instruction to the EPA to "consider" children's multiple exposure is a far cry from the proposal contained in H.R. 4091, for instance, which errs on the public health side of assuming additivity unless other information to the contrary is made available. The export or "Circle of Poison" provisions do not adequately protect countries receiving U.S. exports in two critical ways: (i) pesticides banned or severely restricted in the U.S. because of environmental effects would continue to be exported; and, (ii) pesticides produced but never able to meet EPA registration or tolerance requirements¹⁰ would continue to be exported without any EPA review for adverse effects on human health and the environment. Similarly, provisions that allow for existing stocks of banned or cancelled pesticides to be used up without full evaluation by the Administrator or notice to those purchasing, using or exposed to the products constitute inadequate public protection. Provisions that delay data reviews on so-called "minor use" pesticides and commit taxpayers' funds to conduct pesticide testing for product registration reinforce the government's presumption of pesticide essentiality, instead of breaking new ground for promotion and adoption of alternatives.

Sustainable Alternatives. The Clinton proposal fails to adopt the quantifiable and enforceable pesticide use reduction goals necessary to achieve the kind of reform that is required. We would like to see the transfer of information occur in every crop and region of the country in an organized and deliberate effort to put alternative methods in place.

The requirement in H.R. 4329 to establish a national goal for the adoption of integrated pest management techniques does not provide the kind of incentive-drive and enforceable programs that are needed to move the country away from its current pesticide dependency. This committee has received testimony in the past which shows a disturbing increase in pesticide treated acres. According to Public Voice for Food and Health Policy's 1993 report, in the last decade we have seen a doubling of fungicide use, a steady

⁹Natural Resources Defense Council, White Paper: The Need for a Phase-Out of Carcinogenic Pesticide Residues, September 10, 1993.

¹⁰Sandra Marquardt, et al., *Never-Registered Pesticides: Rejected Toxics Join the "Circle of Poison," Five Case Studies of Pesticides Manufactured by DowElanco, FMC Corp., Miles, Inc., and Monsanto Agricultural Co.*, Greenpeace, February, 1992.

rise in herbicide and fertilizer use and a stable use rate of insecticides.¹¹ Troubling, as well, is the fact that the percent of cropland treated with agricultural chemicals is on the rise.¹² Looking at the poundage of pesticides used alone does not tell the entire story because of the transition in agricultural to highly potent chemicals, such as the sulfonyl urea herbicides, which are now used at application rates that measure ounces per acre.

Legislation must provide clear measurable standards for reductions in pesticide reliance in all pest management systems. Established national goals to move our country off its growing pesticide dependency is central if we are going to effectively respond to the public call for the removal of pesticides that cause adverse effects like cancer.

Conclusion

The July 1992 federal court decision requiring the full implementation of the Delaney Clause has served as a catalyst for congressional action. Rather than embrace the preventive health policy principle of the Delaney Clause and develop a reasoned process to achieve its underlying goals, there has been a rush to defend business-as-usual. We believe a status-quo risk assessment-based approach, as proposed in the Clinton Administration's package, is out-of-step with not only public opinion, but badly miscalculates the need to assist farmers in moving off the pesticide treadmill for simple economic reasons associated with pest resistance, secondary pest infestations, lost pollination and crop damage. At the same time, it severely underestimates the real danger that we face from environmental contamination and preventable diseases such as cancer.

It is our position that proposals which replace the Delaney Clause with a weaker standard of protection must be rejected. Faced with the choice of repeal without a phase-out and enforcement of the law as it currently stands, we would opt for the latter.

The transition to alternatives in agriculture must be accompanied by increased restrictions on the very chemicals that are hurting farmers. While our position stresses the need to look at a range of adverse effects, the importance of attacking cancer causing pesticides is critical in an environment where one in three people contract cancer during their lifetime. This is a national crisis and a true crisis in the farm population. The data is not new

¹¹Allen Rosenfeld et al., *Agrichemicals in America: Farmers' Reliance on Pesticides and Fertilizers*, Public Voice for Food and Health Policy, May 1993, p.6.

¹²Rosenfeld, p.4. The numbers show a distinct trend toward increased dependency on pesticides in agricultural systems. "From 1969 through 1987, the percent of cropland treated with agricultural chemicals increased 131.3 percent for fungicides, 81.3 percent for herbicides, 58.4 percent for insecticides and 32.6 percent for chemical fertilizers."

to this Subcommittee, which has heard testimony on elevated rates of various types of cancers among farmers who use pesticides. Data was presented to this Subcommittee over nine years ago when study results were presented that showed farmers to suffer from significantly higher mortality rates than the general population for the following cancers: stomach, leukemia, lymphatic, multiple myeloma and prostate.¹³ Then, the Subcommittee was told about two separate studies in Kansas (1988) and Nebraska (1990), which examined cases of diagnosed cancer among farmers in the states, established a link between 2,4-D exposure and elevated rates of non-Hodgkin's lymphoma. This linkage has also been documented in Sweden, Canada, Nebraska, and Washington.¹⁴ The first phase of a statistical study conducted by the University of Iowa School of Medicine found that golf course superintendents, who manage areas that represent one of the highest pesticide use areas in the U.S., have a higher than average mortality from a number of cancers, including brain, large intestine, non-Hodgkin's lymphoma, and prostate.¹⁵

These dramatic findings, confirmed year-after-year and study-after-study, call for dramatic action. While the findings call for dramatic restrictions, they also call for dramatic efforts at pesticide use reduction. These restrictions and reductions do not have to be achieved overnight, but in our view they must be achieved through a clear national goal with clear enforceable standards.

We should not fool ourselves about the use statistics and current agricultural dependency on pesticides. Calls for vague plans with even vaguer definitions of Integrated Pest Management (IPM) will not move the reform agenda that is desperately needed and which the American public was told by the Administration was a high priority last year.¹⁶

¹³Leon F. Burmeister, *Cancer Mortality in Iowa Farmers, 1971-78*, JNCI 66(3)461-464 and Statement of Leon F. Burmeister, Professor, Department of Preventive Medicine and Environmental Health, University of Iowa, before the Subcommittee on Department Operations, Research, and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives, May 21, 1985.

¹⁴Sheila Hoar, et al., *Agricultural herbicide use and risk of lymphoma and soft tissue sarcoma*, J. Amer. Med. Assn. 256:1141-47. 1986; S.H. Zahm, et al., *A case-control study of non-Hodgkin's lymphoma and the herbicide 2,4-dichlorophenoxy acetic acid (2,4-D) in Eastern Nebraska*. Epidem. 1(5):349-356; Woods, J.S., *Non-Hodgkin's lymphoma among phenoxy herbicide-exposed farm workers in western Washington state*. Chemosphere 18(1-6):401-406; D.T. Wigle, et al., *Mortality study of Canadian farm operators: non-Hodgkin's lymphoma mortality and agricultural practices in Saskatchewan*. JNCI 82(7):575-582.

¹⁵Burton Kross, Press release on unpublished study, University of Iowa, School of Medicine, 1994.

¹⁶Carol Browner et al., Testimony before Committee on Labor and Human Resources, U.S. Senate, September 21, 1993. On page 24 of the testimony, Ms. Browner stated, "In 1992, a broadly representative group of growers and

In the words of Rachel Carson in *Silent Spring*, "If, having endured much, we have at last, asserted our 'right to know' and if, knowing, we have concluded that we are being asked to take senseless and frightening risks, then we should no longer accept the counsel of those who tell us that we must fill our world with poisonous chemicals, we should look around and see what other course is open to us."

We have an opportunity to join in a national effort to remove toxic pesticides from food production and pest control. Our future rests with clear protective human health and environmental protection standards and a clear commitment to an aggressive national program to assist in the transition to sustainable alternatives not reliant on pesticides.

Thank you.

environmentalists called for a national commitment to promote Integrated Pest Management (IPM). We are setting a goal of developing and implementing IPM programs for 75% of total crop acreage within the next 7 years. We believe Congress should endorse that goal." The executive summary says that the "statute would . . . set a goal for the development of IPM programs and implementation strategies for 75% of acreage within 7 years of enactment."



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Testimony of Joseph M. Schwartz
Associate Director for Policy

Physicians for Social Responsibility

before the House Agriculture Committee
Subcommittee on Department Operations and Nutrition
June 15, 1994

America's costly dependence upon chemical pesticides has more than doubled in the past few decades. Unlike most environmental hazards, pesticides are manufactured to be toxic and are intentionally released into the environment. In addition to widespread examples of environmental pollution, pesticides have bioaccumulated in animals and humans alike. Our bodies still include traces of pesticides banned decades ago. Scientists have long suspected various pesticides of causing various cancers and have begun to associate pesticide exposure with other non-carcinogenic effects, including reproductive disorders, other hormone level disruptions and damage to the nervous system.

Although we know that modern chemical pesticides threaten both the environment and public health, we have only recently begun to appreciate the particular threats these pesticides pose to the most sensitive members of society, infants and children. Although the sensitivity of infants and children to a wide range of environmental contaminants has long been suspected, several characteristics make American children particularly vulnerable to exposure to chemical pesticides. We appreciate this opportunity to address the public health implications--particularly for American children--of the Administration's pesticide reform proposal.

Physicians for Social Responsibility (PSR) has long been concerned with the particular vulnerability of infants and children to environmental contaminants. Disturbed by the presence of strontium-90 in children's teeth, several Boston-area physicians founded PSR more than thirty years ago to publicize the impact of atmospheric testing of nuclear weapons. PSR's work to reduce the public health and environmental risks of nuclear weapons proliferation led to it sharing the 1985 Nobel Peace Prize. PSR includes more than 20,000 members in 90 chapters nationwide and is part of an international network of 250,000 physicians in 76 countries.

A Diagnosis for Reform

Last year, a committee convened by the National Academy of Sciences issued a long-awaited study entitled Pesticides in the Diets of Infants and Children. Both the chair of the NAS committee, Dr. Philip J. Landrigan, and committee member Dr. Richard J. Jackson are members

of Physicians for Social Responsibility's Board of Sponsors. Their committee's report was the most comprehensive look to date at the effects of modern chemical pesticides on the most vulnerable members of society.

The NAS report noted that children's exposure to chemical pesticides may be quite dissimilar even from that of adults within the same home. Children's eating patterns may differ dramatically from those of adults. Children eat more calories relative to body weight than adults do and eat far more of specific foods, also relative to body weight, than adults do. Younger children, in particular, eat a smaller variety of foods than their adult companions, and children who are nursing receive pesticide residues that have concentrated in mothers' milk. Children are also exposed to a wide variety of non-dietary sources of pesticides, such as lawn chemicals, contact with pets, adults exposed in the workplace and even pesticide-treated playground materials, that exacerbate their dietary pesticide exposures. Children, especially newborns, absorb many pesticides more quickly and detoxify many pesticide components more slowly than adults.

The NAS report documented that children's greater sensitivity to environmental contaminants heightens their vulnerability to chemical pesticide exposures. The "unique susceptibility" of infants and children to the toxic effects of pesticides may be due to rapid tissue growth in critical phases of their development, the NAS report noted. (p. 359). Early exposure to pesticides has been implicated in several types of childhood cancers and cancers with long latency periods. In addition to cancer, early exposure to pesticides threatens a wide range of non-carcinogenic effects upon the developing nervous, immune and endocrine systems. "Compared to late-in-life exposures, exposures to pesticides early in life can lead to a greater risk of chronic effects that are expressed only after long latency periods have elapsed." (NAS p. 7).

The report documented recent research that implicated pesticide exposures with impairment of the central nervous system, immune dysfunction and other disruption of normal hormonal development. In particular, the report noted that the central nervous system "may be particularly vulnerable [to the toxic impact of pesticide residues] during a prolonged period of development, even if the exposure is at a level known to be safe for adults." (p. 110). Although EPA has considered some of these effects upon prenatal development, regulators have so far failed to explicitly consider the array of toxic effects of pesticide residues on postnatal development.

To date, EPA has also failed to account for the additive effect of multiple pesticide residues to which children are routinely exposed, the NAS report noted. These multiple pesticide exposures occur from both dietary and non-dietary sources, from multiple sources within children's diets and often on a single piece of food. A report released a few weeks ago detailed that washing, scrubbing and even peeling failed to eliminate multiple pesticide residues from most produce. (Environmental Working Group, Washed, Peeled, Contaminated, May, 1994). The NAS report urged regulators estimating safe levels of pesticide exposure to aggregate all pesticide residues with a common toxic mechanism. (pp. 316, 318-19). "Since the combined effect of pesticides acting by a common mechanism can be greater than the individual effect of any single pesticide, it is important to develop risk assessment methods that address the total risk

from exposure to all pesticides within the same class." (p. 319)

Prescriptions for Pesticide Policy

The ground-breaking National Academy of Science report detailed a pressing need for further research in the area of children's exposure to pesticides. In particular, the report cited a pressing need for additional data on infants' and children' food consumption patterns; on pesticide residues on foods most commonly eaten by infants and children; and on the toxicity of pesticide residues to the developing central nervous, immune and reproductive systems.

Despite the critical research remaining, however, the NAS report concluded that action must be taken now to prevent unnecessary childhood exposure to pesticides. The report insisted that estimates of pesticide residue exposure include both "the unique characteristics" of children' diets and "all non-dietary intake of pesticides." (NAS p. 7) Regulatory determinations of safe levels of exposure, the report noted, must account for physiological factors that place infants and children at greater risk than adults."

Most importantly, the NAS report contended that "[i]n the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children." (NAS p. 9). "Because of specific periods of vulnerability that exist during development," the report added, "an uncertainty factor up to the ten-fold factor traditionally used for fetal developmental toxicity should also be considered for postnatal developmental toxicity *and when data from toxicity testing are incomplete.*" The report concluded that "traditional approaches to toxicological risk assessment may not adequately protect infants and children." (p. 360).

The NAS report offers an invaluable prescription from America's most eminent physicians and public health experts to reform pesticide policy. The question remains: to what extent has the Administration's pesticide reform proposal followed doctors' orders?

The Administration proposal

Overall, the Administration's pesticide reform proposal is well intentioned, but lacks key details. Its overarching goal of reducing America's costly dependence on chemical pesticides is commendable. As any physician will tell you, prevention truly is the best basis for protecting public health. In addition, the Administration's emphasis on the special sensitivity of children is essential.

Elements of the Administration's proposal are worthy of specific attention. Better data collection on foods infants and children eat, pesticide residues in those foods and difference in sensitivity to these residues, will enhance our understanding of the full range of toxic effects of pesticides. Wider application of health standards to raw and unprocessed food and expanding food safety testing from the farm gate through the retail level are also useful. The Administration's goal of strengthening enforcement of pesticide laws has several benefits. Strengthening enforcement will enhance EPA's ability to act quickly against the most toxic pesticides that pose the greatest risk to public health and environmental protection. The public also has a role in acting against the most hazardous pesticides, which the Administration's

proposal wisely recognizes. Although undermined by excess discretion, the Administration's proposal that EPA phase out known hazardous pesticides could promote financial investment, research and development, and farmer use of safer alternatives.

The Administration's pesticide reform proposal, however well intentioned, fails to fully implement several key recommendations of last year's NAS report. Given the current lack of necessary data that the proposal hopes to remedy, its repeated requirement that the Administrator "shall account for available information" in regulatory standard setting could either hamstring EPA pesticide policy reform until further research satisfies a future Administrator or condemn a future Administration to inaction. The NAS report clearly separated the need for additional information from the need to act now to reduce the threat of unnecessary pesticide exposures.

Furthermore, in at least three additional areas, the Administration proposal suggests, but fails to fully implement the recommendations of the NAS report. In each of these contexts--standard setting, multiple exposures and specific testing protocols--the Administration's good intentions are undermined by excess discretion or a willingness to allow a lack of information to perpetuate the dangerous status quo with respect to childhood pesticide exposures. In each context, a competing legislative proposal, H.R. 4091, introduced by Representative Waxman, would remove excess discretion or apply a more protective presumption against continued exposure of infants and children to unnecessary pesticide residues. These provisions lead Physicians for Social Responsibility to believe that H.R. 4091 more accurately reflects the preventive public health recommendations of the NAS report and represents a more effective reform of federal pesticide policy than the Administration proposal.

●Standard setting

Acknowledging the particular vulnerability of infants and children to pesticides, the Administration proposal includes up to an additional 10-fold margin of safety for pesticide residues. Superficially, this provision would implement the recommendation of the NAS report. But the Administration proposal merely provides the additional 10-fold margin of safety to "take into account...the completeness of the data with respect to infants and children." §408(b)(2)(C) The NAS report more explicitly prescribes the additional margin of safety "when data from toxicity testing are incomplete." (p. 361). The Administration proposal should specify that the additional margin of safety shall be applied, absent irrefutable evidence that it is unnecessary.

The Administration proposal provides two risk standards, one for pesticides that may pose a potential dietary risk of cancer and another for pesticides that pose other adverse health effects. Both standards in the Administration proposal are based upon the EPA "taking into account information concerning the special vulnerabilities of children and sensitive populations." §408(b)(2)(A). The Administration proposal provides no additional standards specific to infants or children, despite the NAS report's particular emphasis upon critical phases in postnatal development, during which the effects of pesticide residues may be especially toxic. Instead, H.R. 4091 specifies that a pesticide "not cause or contribute to the disproportionate accumulation of cancer risks during the first five years of life." §3(b).

●Multiple exposures

The NAS report concluded that "[a]ll sources of exposure to pesticides--dietary and non-dietary--need to be considered." (p. 360) The Administration proposal notes that EPA "shall fully account for available information on the cumulative effect of such residue and any chemically or pharmacologically related substances in the human diet, and other ways in which the consumer may be exposed to such residues...including, to the extent data permit, through drinking water." §408(b)(2)(B)(iv). More specifically, the proposal would require EPA to "assess the risk of the pesticide chemical residue based on...available information concerning the cumulative effects on infants and children of such residues and other substances that have common mechanisms of toxicity." §408(b)(2)(C)(i)(III).

Although appearing to satisfy the NAS recommendation, a lack of available data would continue to allow a pesticide the benefit of the doubt in the Administration's proposal. Instead, H.R. 4091 would prevent unnecessary childhood exposure to pesticide residues by requiring EPA to treat pesticides that are "pharmacologically related or have a common toxic mechanism or effect" as having "an additive deleterious effect, in the absence of evidence to the contrary." §3(b). This provision--omitted from the Administration proposal--would implement the NAS report's recommendation that "in the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children." (p. 9)

●Child-specific testing protocols

Although the Administration's proposal seeks additional data on the effects of pesticides on children, it requires no specific protocols for tests to assess whether a pesticide poses particular risks to children. Given the absence of relevant data and the known vulnerability of children to pesticide residues, the NAS report endorsed more ambitious testing protocols to protect children from unnecessary pesticide exposures. Unlike the Administration bill, H.R. 4091 would do more than collect additional data for general determinations of whether a pesticide might compromise the "special vulnerabilities of children and other sensitive populations." H.R. 4091 would require EPA to develop protocols for tests that would specifically determine whether a pesticide poses particular risks to infants and children. This provision--omitted in the Administration proposal--would ensure that pesticide data submitted to EPA satisfy children-specific safety requirements.

Conclusions

Pesticides are ubiquitous in Americans' diets and in our environment. The toxicity and sheer volume of pesticides used in the United States has grown dramatically since the Second World War. Not all pesticides are equally toxic; neither are all pesticides now used equally necessary to the continued prosperity of American farmers. Although we lack a great deal of information about the long-term toxic effects of pesticides, especially with respect to infants and children, last year's NAS report on Pesticides in the Diets of Infants and Children documents that we know enough now to reform America's costly dependence upon modern chemical pesticides.

While researchers continue to provide essential information on the effects of pesticide exposures, prudent public health measures warrant protections against excessive exposure to

pesticide residues, especially by infants, children and other vulnerable populations. The Administration's pesticide reform proposal would advance our understanding of the full range of hazards to which modern chemical pesticides have placed American consumers. If implemented conscientiously, the proposal could slowly reduce America's dangerous and costly reliance on pesticides.

In several important respects, however, the Administration's proposal--while echoing the language of the seminal NAS report--would not ensure that the report's recommendations would be fully implemented. In its current form, the Administration proposal would not fully protect public health from toxic pesticide exposure. Physicians for Social Responsibility looks forward to working with you and other members of Congress to craft pesticide reform legislation more fully protective of public health and the environment.

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Statement of

Ms. Juanita Duggan

Senior Vice President, Government Affairs

NATIONAL FOOD PROCESSORS ASSOCIATION

before the

House Agriculture Subcommittee
on Departmental Operations and Nutrition

on

H.R. 4362

"Pesticide Reform Act of 1994"

H.R. 4329

"Federal Insecticide, Fungicide, and
Rodenticide Act Amendments of 1994"

and

H.R. 1627

"The Food Quality Protection Act of 1993"

June 15, 1994

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE, I am

Juanita Duggan, Senior Vice President for Government Affairs of the National Food Processors Association (NFPA). NFPA appreciates the opportunity to appear today and to address the important topics of pesticide regulation and food safety. We commend the Chairman's leadership in holding a hearing on pesticide reform legislation and in providing a forum for discussion of the critical pesticide policy choices facing EPA.

NFPA is a national trade association representing over 500 companies, including food processors, and food packaging and equipment manufacturers. NFPA maintains and operates three research laboratories, employing over 80 Ph.D.'s and other scientific personnel involved in a wide range of food processing research, including pesticide residue analysis and investigation.

NFPA represents the vast majority of fruit and vegetable processors in the United States, including processors of many minor crops. Consequently, NFPA has a vital interest in pesticide regulatory procedures and food safety standards. NFPA strongly supports programs to develop economical and effective alternatives to pesticides. The food processing industry is making concerted efforts to develop alternative pest control techniques, including biological, cultural and mechanical controls, to support integrated pest management (IPM) programs and to minimize pesticide use. NFPA supports further research and funding of these efforts, as well as steps to facilitate EPA registration of effective biological control agents to further reduce pesticide use. It is important to recognize, however, that, even with ongoing efforts to reduce pesticide use, the responsible use of pesticides will continue to be necessary for the production in the United States of an adequate, wholesome and nutritious food supply.

Consistent with the recommendations of the 1987 National Academy of Sciences (NAS) "Delaney Paradox" Report, NFPA supports statutory changes to establish a uniform negligible risk standard for pesticide tolerances for raw and processed food, and to give EPA sufficient authority to take into account the best available scientific information in tolerance decisions. The Court of Appeals decision in Les v. Reilly confirms the need for legislation giving EPA additional flexibility in tolerance decisionmaking in light of modern advances in safety testing and risk assessment methodology.

NFPA supports reasonable efforts to reform the pesticide regulatory process, as well as to resolve the Delaney paradox. We support legislation that streamlines the procedure for removing hazardous pesticides from the market, promotes sound scientific judgment in pesticide tolerance decisions, assures that tolerance decisions are based on accurate exposure data, requires renewal of pesticide tolerances to assure compliance with current safety standards, facilitates minor use registrations and provides for national uniformity of pesticide tolerances.

Consistent with these objectives, NFPA strongly supports the Lehman-Bliley-Rowland bill (H.R. 1627), which has broad bipartisan support in the House, and the counterpart bill (S. 1478), introduced by Senators David Pryor and Richard Lugar. We believe these bills provide the best vehicle for pesticide reform. These bills would make important improvements in both the federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the federal Food, Drug and Cosmetic Act (FD&C Act). They would streamline the pesticide cancellation and suspension processes, establish a

consistent negligible risk standard for pesticide tolerances for raw and processed food, assure appropriate consideration of pesticide benefits and provide for national uniformity for tolerances meeting current safety standards. Moreover, S. 1478 contains specific provisions, which we strongly support, that would require EPA to implement recommendations described within the recent NAS Report on Pesticides in the Diets of Infants and Children.

The strength of H.R. 1627 and S. 1478 are reflected by the fact that they are endorsed by a broad coalition of food industry organizations, including growers, processors and retailers, and have attracted the support of 222 members of the House. The bills provide a solid foundation from which to enact reasonable food safety legislation.

The Administration recently released its own legislative proposals for pesticide reform. The focus of my testimony this morning will be to explain NFPA's opposition to the Administration's proposals. The Administration's bill would restrict, rather than enhance, EPA's ability to employ the best scientific evidence in tolerance decisions. Moreover, the Administration's bill would go far beyond reform of pesticide tolerance standards, as recommended by the NAS, and would eliminate consideration of pesticide benefits, revise most major FIFRA procedures to reduce public participation rights and scientific review requirements, grant multiple additional enforcement powers to EPA and FDA, and authorize citizen suits in a variety of contexts. There is no demonstrated need for such a total overhaul of FIFRA. Moreover, the Administration's bill does not address an issue of critical importance to

the food industry: national uniformity of pesticide tolerances. The broad, sweeping amendments in the Administration's bill are contrary to the interests of the food industry and consumers, and would serve to accelerate the loss of safe and effective minor use pesticides, which are of particular importance to our members.

We have made it clear that we support a uniform negligible risk standard for pesticide residues in raw and processed food, but not at the expense of scientific reason, regulatory order and consumer welfare. It makes no sense to replace the Delaney Clause with an equally rigid and arbitrary safety standard, to superimpose a different tolerance reevaluation schedule on top of the FIFRA reregistration process, to abandon consideration of benefits in tolerance decisions, or to impose further data requirements and cost pressures on minor uses.

The Administration has argued that immediate legislative action is needed to avoid the potential "crisis" created by the Ninth Circuit Court decision in Les v. Reilly. The Agency would have the Congress believe that unless immediate legislative changes are made the Agency will have no choice but to revoke tolerances for a large number of valuable pesticides with serious adverse consequences for agriculture and the food industry. In fact, however, the Agency's hands are not tied by Les v. Reilly. EPA has sufficient authority under existing law to regulate pesticide tolerances in a manner that would minimize the impact of the Delaney Clause, and there is no need to consider food safety legislation in a crisis atmosphere.

The potential devastating loss of agricultural pesticides threatened by EPA is not a necessary result of the Les v. Reilly decision but of EPA's concentration and

coordination policies. These policies are an EPA invention that has never been properly adopted as a regulation and should be abandoned. EPA's concentration policy requires issuance of a section 409 food additive tolerance whenever there is a possibility that a pesticide residue might concentrate in a processed food and its coordination policy mandates that, if a section 409 tolerance cannot be issued (because of the Delaney Clause or otherwise), EPA must also revoke the section 408 raw product tolerance and cancel the underlying pesticide registration for the pesticide.

In September 1992, NFPA, the United Fresh Fruit and Vegetable Association, and other groups filed a petition urging EPA to rescind its concentration and coordination policies and no longer to require separate 409 tolerances for pesticides in processed food. The NFPA petition urges EPA to follow the language and intent of the "flow-through" provision of the FD&C Act, which provides that a pesticide residue in processed food when ready to eat is lawful as long as the residue is not greater than the tolerance for the raw commodity from which the processed food is made. The NFPA petition demonstrates that the EPA policy was never envisioned by Congress, and is based upon erroneous factual assumptions. Extensive data submitted in support of the petition show that actual residue levels in agricultural commodities and in processed food are well below raw product tolerances. The petition demonstrates that continuation of current EPA policy will require numerous costly tolerance revocation proceedings, will force the agency to prohibit the use of beneficial pesticides that pose trivial risks and will thereby reduce the availability and increase the cost to consumers of nutritious fruit, vegetable, and grain products, at the very time that FDA and the

medical community are recommending greater consumption of these foods to prevent disease. There, thus, is no sound legal or public policy basis for EPA to continue its concentration and coordination policies, and EPA should not be permitted to perpetrate these policies to create an artificial pesticide crisis.

Although we believe that focused and reasonable legislation is the best way to reform the pesticide tolerance system, the Administration's bill is clearly the wrong vehicle for this purpose. The Administration bill does little to improve the pesticide tolerance system, while incorporating numerous unnecessary and unjustified changes to FIFRA. Our specific objections to the Administration bill and reasons for favoring the LBR bill include the following:

1. Overly Conservative and Rigid Food Safety Standard

The Administration bill would impose an overly conservative and rigid safety standard for pesticide tolerances. The bill would require a separate safety standard for potential carcinogens, broadly defined to include any pesticide found to induce cancer in man or animals, or found to pose "a potential dietary risk of cancer in humans". The bill would specify the safety factors, uncertainty factors, and exposure assumptions that must be used in risk assessment, including the use of a ten-fold safety factor and special risk factors for infants and children. This inflexibility in risk assessment methodology would generate exaggerated risk estimates and undermine the soundness of regulatory decisionmaking. It would inhibit the EPA's ability to exercise expert judgment, to take account of evolving scientific standards and to consider all relevant safety and exposure information. H.R. 1627, on the other hand, assures a

science-based standard for pesticide tolerances and therefore represents the better approach to resolving the Delaney Clause problem.

2. Exaggerated Exposure Assumptions

The Administration bill would require EPA to use worst case exposure assumptions in tolerance determinations. EPA would be required to assume that food contains pesticide residues at full tolerance levels and that 100 percent of each crop is treated. Extensive data collected by FDA, USDA, and the food industry over the past decade, show that these assumptions are inaccurate, that pesticide residues in raw foods are far below tolerance levels and that residues in processed foods are often undetectable.

Under the Administration bill, actual crop treatment data could only be used in exposure assessments where a registrant could prove that no subpopulation group had higher exposure, and this determination would be subject to reevaluation at least every five years. This would effectively preclude use of realistic pesticide exposure data. The bill's artificial exposure assumptions would generate highly inflated risk estimates and would lead to unnecessary loss of many valuable pesticides, particularly for minor uses. By contrast, under H.R. 1627, EPA would be required, to the extent possible, to calculate dietary exposure on the basis of the percent of food actually treated with a pesticide, and on the basis of the actual residue levels detected in the food.

3. Establishment of Unnecessary Multiple Tolerances For A Pesticide On A Single Food

Under the Administration's bill, EPA would be authorized to set multiple tolerances for a pesticide on a single food at different points in the distribution chain (*i.e.*, at harvest, at retail and after processing). In addition, the bill would authorize EPA to establish numerous separate tolerances for different processed forms of the same food. This would impose unnecessary additional registration burdens on pesticide companies and would create substantial enforcement difficulties for FDA. There is no need for a multiple tolerance system, and the public is likely to be confused by establishment of separate tolerances for a single pesticide on different forms of the same food.

Moreover, the Administration bill would require tolerances or exemptions for each pesticide chemical residue in food, including each substance that is present in food as a result of the metabolism or other degradation of a pesticide chemical. By contrast, H.R. 1627 would codify EPA's existing policy of considering pesticide metabolites and degradation products to be subject to the established tolerance for the precursor chemical, unless EPA has determined that the metabolite or degradation product is likely to pose different or greater health risks. The approach taken under H.R. 1627 would avoid the increased registration costs, administrative burdens and enforcement complexities of establishing multiple separate tolerances for metabolites and degradation products where there is no valid public health reason for doing so.

4. Elimination of Benefits Considerations In Tolerance Decisions

The Administration bill would greatly limit the types of benefits that could be considered in pesticide tolerance decisions, would prohibit the continuation of a tolerance based on exceptional benefits beyond five years, and would prohibit any consideration of benefits in tolerance decisions after ten years. The bill would prohibit EPA from taking into account the value of a pesticide in maintaining an adequate, wholesome and economical food supply even though scientists and public health authorities now agree that adequate consumption of fruits and vegetables is a critical factor in disease prevention. Prohibition of consideration of benefits for pesticide tolerances would deprive growers of pesticides for which there are no alternatives, would undermine the health and welfare of consumers and would not achieve a meaningful risk reduction.

The Administration bill would permit consideration of benefits during a limited transitional period only where it could be proven that loss of a pesticide would cause "a significant disruption in domestic food production". This narrow standard would ignore substantial regional or seasonal disruptions and would effectively preclude benefits considerations.

The Administration's proposal to eliminate benefits considerations in pesticide tolerance decisions is inconsistent with the basic registration standard under FIFRA and contravenes the fundamental policy set forth in Section 1 of the Administration's own Executive Order 12366, which directs federal agencies to consider

the costs and benefits of available regulatory alternatives and to adopt approaches that "maximize net benefits" to society.

5. Decoupling Of Tolerance Reviews From FIFRA Reregistration

The Administration bill would require EPA, within 180 days of enactment, to review all existing pesticide tolerances and to identify each tolerance which does not appear to meet the requirements of the law. EPA would be required to call-in data and make a final determination with respect to most such tolerances within a three year period. This accelerated review provision is impractical, would conflict with the FIFRA reregistration process and would give EPA discretion to eliminate valuable food use pesticides without adequate procedural protections or a determination of unreasonable risk. Accelerated tolerances renewal would impose heavy burdens on EPA and pesticide registrants, and would create additional pressures for registrants to decline to support valuable food use pesticides. By contrast, H.R. 1627 would synchronize the schedule for reregistration and tolerance review decisions to ensure that EPA's tolerance decision-making benefits from the data being developed under the reregistration process.

6. No Tolerance Uniformity Provision

Under H.R. 1627, states and political subdivisions would be precluded from issuing different tolerance limits, warning requirements, or other restrictions on pesticide residues in food, for pesticides registered or reregistered by EPA after April 25, 1985. This would secure EPA leadership in pesticide tolerance decisionmaking and would avoid the consumer confusion and substantial burdens on interstate commerce

caused by special state requirements. Consumer protection would be assured by limiting required uniformity to pesticide tolerances supported by full scientific testing and recent EPA approval. States would be permitted to petition EPA for approval of a different tolerance on the basis of compelling local conditions. The Administration bill contains no national uniformity provision, thus inviting states to issue different and conflicting tolerance limits, which would undermine the federal regulatory system.

7. No International Harmonization Provision

H.R. 1627 would require EPA, in establishing a pesticide tolerance, to take into account CODEX recommended international residue limits and to explain any departure from the CODEX limits. Setting U.S. tolerances consistent with established CODEX limits, where adequate safety data is available, would foster harmonization of international pesticide standards and would promote increased international trade in agricultural products. In spite of the Administration's professed commitment to international harmonization, the Administration bill does not contain a comparable provision.

8. Unnecessary Expansion Of FDA Enforcement Authority

The Administration bill would grant FDA broad new enforcement power, including recall, embargo and civil penalty authority, with respect to pesticide tolerance violations for food products. FDA would be empowered to embargo food products for up to 30 days and to require immediate recall of food products on the basis of a "reason to believe" that the product is adulterated without any right to a preenforcement hearing or review, and regardless of the magnitude of the alleged violation. Civil penalties of

up to \$250,000 per violation could be imposed against companies for any pesticide tolerance infraction, regardless of whether a potential health risk were involved. FDA already possesses ample enforcement power, including seizure, injunction and broad criminal penalty authority. There is no demonstrated need to grant FDA additional enforcement authority for pesticide tolerance violations.

9. Ill-Considered Phase-Out Authority

The Administration bill would grant EPA new authority to "restrict, reduce or eliminate" the use of a pesticide where "credible scientific evidence" indicates that use of the pesticide is reasonably likely to pose a significant risk to humans or the environment. This would empower EPA to limit or prohibit the use of a pesticide without the external scientific review and procedural protections guaranteed under the cancellation process, without any consideration of the pesticide's benefits, and on the basis of evidence that is too weak, incomplete or inconsistent to support a cancellation. Phase-out orders would generate damaging adverse publicity, disrupt sales of food products and cause irreparable harm to food producers and consumers.

Phase-out authority is unnecessary. Existing proposals to streamline the cancellation process would provide ample authority for prompt cancellation of pesticides that pose demonstrated risks and would assist in promoting consumer confidence in the food supply.

10. Citizen Suits

The Administration bill would authorize any person to bring a lawsuit in Federal court against EPA, a pesticide registrant or any pesticide user, except for a

farmer, for any alleged violation of FIFRA or of any EPA pesticide regulatory requirement. This provision would increase the litigation burdens of Federal courts, would interfere with EPA's enforcement prerogatives and would subject pesticide producers and users other than farmers to expensive and burdensome lawsuits.

11. Whistle Blower Provision

The Administration bill would give broad legal rights to any employee who alleges that he has been terminated, or that his employment status has been adversely affected, in retaliation for his bringing a legal action, or threatened legal action, for an alleged FIFRA violation. This provision would impair employer-employee relationships and impose further unnecessary burdens on employers and agricultural producers.

12. Revised Suspension Procedure

The Administration bill would eliminate the current right of pesticide registrants for an expedited hearing on a proposed suspension order. EPA would be authorized to suspend a pesticide registration without a hearing for 180 days. If a cancellation proceeding was initiated within the 180 day period, the suspension would remain in effect until the completion of the cancellation process. This provision would give EPA excessive discretionary authority, would deny registrants a fair hearing and would cause irreparable harm to food producers who market products containing a suspended pesticide. Post-suspension court review, as provided for in the bill, would not offer a meaningful substitute for a pre-suspension hearing.

Proposed improvements to the cancellation procedure will give EPA sufficient power and flexibility to remove hazardous pesticides from the market in a timely manner. In true emergencies, EPA would retain its current authority to suspend a registration pending the conclusion of the expedited hearing.

By contrast, H.R. 1627 would retain existing suspension procedures, but would authorize EPA to issue an emergency suspension order before issuing a proposed cancellation notice. This would permit EPA to take prompt action against truly hazardous pesticides without the delay inherent in developing the full risk/benefit evaluation required for a cancellation notice. This provision, coupled with the 1988 FIFRA amendment which eliminated EPA's obligation to indemnify owners of existing stocks of suspended pesticides, would provide EPA sufficient authority to suspend registrations for pesticides that pose a true imminent hazard. EPA has shown no justification for granting the additional extraordinary suspension authority in the Administration bill.

13. Burdensome Fees

The Administration bill would require EPA to collect fees to cover the costs of administering the pesticide tolerance provisions of the Act, and would amend FIFRA to mandate additional reregistration and maintenance fees for food use pesticides. User fees of this kind unfairly penalize the regulated industry, undermine confidence in EPA's enforcement integrity and create additional disincentives for registrants to support valuable food use pesticides, particularly for minor crops.

* * *

We commend the Subcommittee for opening a dialogue on pesticide reform and we stand ready to work with the Congress to develop food safety legislation that will give EPA the tools necessary to reach reasonable and scientifically defensible tolerance decisions. The Administration bill is not, in our view, the right vehicle for achieving this goal. We strongly believe that H.R. 1627 offers a reasonable, balanced and focused pesticide reform package, and we urge this Committee to adopt H.R. 1627 as the model for crafting any legislation.

TESTIMONY OF
JAY J. VROOM, PRESIDENT
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

COMMITTEE ON AGRICULTURE

UNITED STATES HOUSE OF REPRESENTATIVES

JUNE 15, 1994

Mr. Chairman and members of the Subcommittee:

On behalf of the member companies of the National Agricultural Chemicals Association (NACA), I would like to thank the Subcommittee for the opportunity to comment on H.R. 4362 (the "Pesticide Reform Act of 1994"), and H.R. 4329 (the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1994"). As you know, NACA is the not-for-profit trade organization of U.S. manufacturers, formulators and distributors of agricultural crop protection and pest control products. Our membership is composed of those companies which produce, distribute and sell virtually all of the active compounds used in crop protection chemicals registered for use in the United States. Clearly, NACA's members have a vital interest in continuing to improve the processes which govern the testing, review, and approval of their products. These comments discuss the improvements to the present system which are truly needed, the consequences of not making those improvements, and how the specific proposals in H.R. 4362 and H.R. 4329 will, or will not, result in overall improvement.

I. The Need for Legislation.

The current legislative debate exists because the science which supports pesticide regulation has continued to evolve, while the laws and regulations governing pesticides largely have not. At the root of this debate is the 1958 "Delaney" clause, an anachronism which not only renders the FFDCA internally inconsistent, but also conflicts with FIFRA, the primary statute under which pesticides are regulated. NACA believes that there are two ways to resolve this inconsistency: Congress can modernize the FFDCA by eliminating the Delaney clause (replacing it with a single negligible risk standard for raw and processed food as recommended by the NAS in their 1987 report "The Delaney Clause"), or EPA can modernize its policies which implement the Delaney clause (including an affirmative ruling on "the NFPA" petition). Either option will largely avoid the disruption to American agriculture which some have predicted if action is not taken.

This is not to say that other aspects of our pesticide laws could not benefit from improvement. To the contrary, through the ongoing legislative debate several areas of general agreement have emerged among EPA, the regulated community, and environmental activists. Areas of agreement include:

- Delaney's "zero-risk" standard is no longer scientifically justified, is virtually impossible to achieve, and should be replaced with a negligible risk standard.
- A single standard must be set for raw and processed food. Current law treats them differently, and this makes neither scientific nor regulatory sense.
- Newer products, developed using state-of-the-art research and understanding, must be brought more quickly to the market. NACA has worked closely and effectively with EPA

to improve certainty and efficiency in data requirements, and this process must continue.

- The administrative process for removing problem pesticides from the market takes too long. We need a new process that can allow EPA to take action quicker, while preserving essential due process rights.
- Re-registration is taking too long. The burden on EPA of reviewing mountains of data is staggering, but the task is essential to public safety and confidence. All parties have agreed that delays in this process serve no one, and real improvement must be found.
- Adverse effects from the loss of minor use pesticides are real, and growing. As Chairman de la Garza well understands, this issue must be addressed.
- The process for making routine improvements in pesticide usage, such as minor label changes, could be improved.

While these issues are important, the single issue which brings us together year after year is repeal of the Delaney clause. If Congress cannot resolve that issue this year, the job of implementing Delaney in the wake of the Les v. Reilly decision will fall squarely upon EPA. As explained below, EPA has shown little willingness to reconsider old policies, or to incorporate modern scientific principles into its Delaney-implementation plans.

II. EPA Appears Prepared to Preside Over a Regulatory "Train Wreck"

One apparent consequence of the Les v. Reilly decision on Delaney policy is the review, and possible revocation, of a number of valuable food use tolerances. Because EPA may no longer utilize a *de minimis* exception to the Delaney clause when making tolerance decisions

under the FFDCA, tolerances previously granted under that exception must be reviewed to determine whether they violate a strict reading of Delaney. However, rather than determining whether their pre-Les policies are still justified (or legal), and rather than focusing on the ramifications of not reviewing those policies, EPA has instead concentrated its efforts entirely on obtaining a "legislative solution." This blind focus on legislation unnecessarily places the entire burden of reform on Congress. EPA should reevaluate what it can do to practically, and legally, implement existing law. Without such a reevaluation, EPA will create confusion, lose additional public confidence, and cause significant unnecessary disruption to agriculture.

For instance, EPA has consistently interpreted the Les decision in the most expansive manner possible, claiming that the decision itself actually requires specific regulatory actions, including the revocation of tolerances and cancellation of registrations. While denying that existing tolerances are a public health concern, EPA has warned that without sweeping legislative reform it will be forced to revoke dozens of needed tolerances, causing widespread disruption of agriculture, food processing, and pesticide industries.

Yet EPA continues to overlook the plain language of other sections of the FFDCA which would decrease the adverse effect of the Les decision on agriculture and the American public. EPA also has failed to implement policy changes which would reconcile agency practice with current law, and allow the agency to focus scarce resources on areas of true concern. Many now believe that EPA has deliberately chosen to ignore these statutes and policies in order to create pressure for their many legislative recommendations. This tactic will also allow EPA to avoid responsibility when it begins to revoke large numbers of tolerances, and agricultural markets are disrupted.

EPA claims it has two options: massive tolerance revocation, or their legislative recommendations. In fact, there are at least six non-legislative strategies to avoid significant disruption, all consistent with current law:

1. Grant the "NFPA Petition." In the fall of 1992, the National Food Processors Association (NFPA) and others filed an administrative petition asking EPA to (1) abandon its concentration and coordination policies (because they are illegal, and amount to improperly promulgated regulations), and (2) recognize the "flow through" provision of FFDCA §402. The petition was not published for comment until February of 1993. Although a response is not required by a specific date, nearly two years have now passed without EPA action. Ignoring comments on the petition filed by hundreds of affected parties, Assistant Administrator Goldman glossed over the importance of the petition in testimony before Congress on October 29, 1993, stating that EPA was "reluctant to break new ground administratively" with the "interpretations" suggested by NFPA. This statement reflects a dangerous and unlawful unwillingness to consider proposals on non-legislative solutions to the predicament caused by the Delaney clause.

2. Rescind its Policy of Intentional Inaction. On April 6 of this year, EPA announced via Federal Register notice that it had ceased review and processing of tolerance petitions, as well as the associated FIFRA registration applications, if any of the uses "appear" to result in a residue that needs a food additive regulation which Delaney would bar. Without actually making a fact-based finding, EPA has arbitrarily blacklisted products and completely disregarded the rights of registrants and the needs of growers. Of course, the primary importance of this policy will be to slow, if not stop outright, the

introduction of several newer and possibly safer pesticides. In so doing, EPA has illegally read the Delaney standard into both FIFRA and Sec. 408 of the FFDCA, and denied registrants the opportunity to adequately defend their products before either the public or EPA.

3. Reconsider Outdated Policies. Many of the policies EPA has adopted in order to implement FIFRA and FFDCA mandates include unrealistic, conservative assumptions and unnecessarily stringent definitions. In some cases, the policies lead to contradictory results. For instance, many Sec. 409 tolerances are required for foods which are not commonly understood to be "processed." While EPA has proposed redesignating dried hops as a raw food, it did so only after being required by Congress to do so in an appropriations bill. To date, EPA has failed to take similar action for dried raisins and figs. Additionally, current EPA policy requires Sec. 409 tolerances for many food byproducts, even if they represent only a small portion of the food in an animal's diet. Although the law requires a tolerance only if the byproduct "is a substantial source of nutrients in the diet of the animal," EPA requires a tolerance for all such byproducts, even though many are no longer used in animal feeds (e.g. dried apple and grape pomace, and dried citrus pulp), or constitute only an insignificant part of the animal's diet.

Other areas EPA has failed to address include (1) the "ready to eat" language of FFDCA, which, if given effect, would lead to more realistic exposure and risk (and therefore tolerance) assumptions, and (2) EPA's continuing focus on the theoretical possibility of concentration rather than on actual data or residues. Challenges to all of these outdated policies have been pending before EPA -- unanswered -- since at least

September of 1992.

4. Recognize Advances in the Understanding of Cancer. EPA's reliance on overly simplistic category-based definitions of carcinogenicity fails to consider advances in scientific understanding, unique properties of various compounds, and mechanisms of action that may differ from one compound or test subject to another. Use of Maximum Tolerated Dose ("MTD") testing in regular protocol, and routine reliance on exaggerated exposure assumptions leads to results which have no real world significance, and are irrelevant to a determination of whether a compound "induces cancer ... in man ... by tests which are appropriate for the evaluations of the safety of food additives," and contribute to loss of consumer confidence in food safety. Other countries with modern scientific and regulatory systems no longer rely solely on MTD.

5. Rule on the Objections and Hearing Requests Filed by the Registrants in the Les Case. EPA announced last August that it intended to revoke the seven tolerances involved in the Les decision. That announcement failed to first give the registrants an opportunity to present evidence on whether the residues did in fact concentrate above the level of the raw product tolerance, or whether they "induce cancer" within the meaning of the Delaney clause. Thereafter, registrants and other interested parties filed objections, and requests for stays and hearings, claiming that their rights to supply data and make legal and factual arguments against revocation had been violated. To date, EPA has not acted on any of those requests, creating legal, market and consumer uncertainty. Worse, EPA has recently announced that it intends to revoke upwards of 70 additional tolerances in the same manner.

6. **Revise the Current "Sec. 18" Policy.** EPA's first act implementing the Les decision was not against the tolerances named in that case. Instead, EPA moved against the FIFRA Sec. 18 "emergency" exemptions that farmers need to address unforeseen pest damage, for which alternative defenses often do not exist. On May 7, 1993, EPA revoked five existing Sec. 18 tolerances, and denied applications for 16 others because they "appear to meet" the Delaney clause "induces cancer" standard. This action was taken without actual findings that the residues in fact "concentrate" or "induce cancer" in violation of the Delaney clause, and without notice or opportunity for comment, as the FFDCA and the Administrative Procedure Act would require.

EPA acknowledged that its action would have an adverse impact on growers of up to \$70 million in 1993 alone. Those losses, and impacts such as product "blacklisting" and loss of needed, effective products could have been mitigated if EPA had first (1) determined whether the residue actually violated the Delaney clause, (2) resolved the tolerances at issue in Les, or (3) addressed the issues then still pending in the NFPA petition. Instead, EPA embarked upon a course designed to create the need for their particular legislative agenda, even saying boldly at the time that "The necessity of this [action] highlights the need for new legislation that addresses food safety. The Clinton administration will ... develop a proposal." At that time, at least two separate proposals were already pending before Congress.

EPA could easily extricate itself from the massive administrative challenges it faces, avoid putting food production at risk, insure the public safety, and do so in full compliance with existing law and regulations if it were to:

- Grant the NFPA petition. Current concentration and coordination policies are illegal and no longer justified;
- Rescind its policy of intentional inaction.
- Abandon outdated policies (including definitions of "raw" and "processed" foods, and implementing the "flow-through" and "ready to eat" provisions of FFDCA), and redefining what "induces cancer" means for purposes of the Delaney clause;
- Stop regulating on the basis of exaggerated risks and assumptions;
- Respond to the objections, and grant the stay and hearing requests sought by the registrants and NACA in the Les tolerance revocation action; and
- Rescind the Current Sec. 18 policy, or make it applicable to only those products which **in fact** are prohibited by Delaney.

II. NACA's Response to H.R. 4362 and H.R. 4329

NACA well appreciates the time, effort and attempts at inter-agency coordination which have gone into development of the Administration's FIFRA/Food Safety proposal. However, by bringing omnibus new legislation to virtually every aspect of pesticide regulation, the bills amount to a wholesale overhaul. Rarely will a system which needs improvement be helped by adding layers and layers of untested new authority. By failing to focus on the areas of true concern, these bills will have the unintended affect of bringing the registration of new products (and the reregistration of existing products) to a halt, and they may not actually speed the removal pesticides found subsequently to exceed society's acceptable risk/benefit standard. They

will, however, clog EPA and the courts with citizen suits and other litigation, and create confusion among EPA staff, the regulated community and public when EPA attempts to act under one or more of the multitude of new authorities.

Nevertheless, NACA will address each of the major components of the two bills, and explain why many of their provisions will not assist in the overall objective of improving the system of pesticide regulation, or the safety of America's food.

A. FFDCA AMENDMENTS (H.R. 4362)

Risk Standard for Tolerances. Under the Administration's proposal, a tolerance may be established for a raw or processed food if the residue is "safe." Safety is then defined as presenting "a reasonable certainty of no harm" when evaluating risks from cancer, risks other than cancer, and establishing tolerances for children and other sub-populations. Because it would fundamentally alter the standard for evaluating tolerances, the public deserves to understand precisely what this standard means, how it will be interpreted, and what the net effect will be on individual existing tolerances.

For instance, the definition of "safe" was taken from a section of the Code of Federal Regulations dealing with food additives. However, there is language in that definition which acknowledges that "intended conditions of use" are relevant, and that it is "impossible to ... establish with complete certainty the absolute harmlessness of the use of any substance." NACA is curious why the entire definition was not taken. Furthermore, the plain language of the phrase "no harm" appears to establish a zero-risk standard. If so, this bill merely replaces the Delaney

clause with another "zero-risk" standard. While we appreciate that EPA has proposed replacing the Delaney clause with a single risk standard, NACA is very concerned with what this new standard means, and how it will be interpreted.

This committee understands that the current system for setting and maintaining tolerances is a "health-based" system. Consequently, the Administration's ongoing pleas for a "health-based" system are patently misleading. Pesticides are among the most heavily researched and regulated products on the market today. Before a pesticide may be registered for use, manufacturers must perform over 120 tests designed to protect human health and the environment. The registration standard requires protection of "human health," and pesticide tolerances are NOT set at particular levels in order to provide agricultural benefits. Although improvements are always welcomed (and have been continuously added under current law), we have a strong health-based system in place today.

Elimination of Benefits Consideration. Although the Administration has never explained why limited consideration of benefits poses a public health concern, its bills preclude consideration of pesticide benefits when establishing tolerances and in regulating pesticide use. Although an extension of time for an existing tolerance may technically be granted using benefits, that extension would be virtually impossible to obtain. For instance, the registrant would have to show that loss of that particular tolerance would "severely disrupt domestic food production." Rarely, if ever, would loss of one product tolerance create a nationwide disruption. But over time, this provision could severely affect agriculture through the attrition of "a thousand paper cuts" which together would be devastating. Furthermore, proposals on so-called "label call-in" and "phase-down/phase-out" would eliminate consideration of pesticide benefits altogether.

Lost in both bills is the concept that decisions regarding risk cannot be accurately made without also evaluating the benefit which acceptance of that risk provides. A detailed consideration of benefits -- which comes into play only when test results are very close to the safety standard -- allows EPA to make informed decisions. After all, blind reliance on numbers alone is responsible for the Delaney dilemma we face now. Congressional debate concerning the value of a cost/benefit analysis in other legislation this year has shown that it is an extremely important undertaking.

Overly Restrictive Standards for Children and Sub-populations. Last summer's NAS report made several basic recommendations, including that more/better data be developed on pesticide use and on the foods children eat; that additional toxicity testing procedures be developed which evaluate the vulnerability of infants and children; and that improvements be made in the risk assessment process. NACA largely agrees with these recommendations, as does the 220-member Food Chain Coalition through the legislation which they support.

However, in subtle but important ways this bill goes beyond the recommendations of the NAS. For instance, the NAS recommended an additional 10-fold safety factor for infants and children for those instances where "there is evidence of postnatal developmental toxicity, and ... data from toxicity testing relative to children are incomplete." By contrast, this bill requires the additional safety factor as a matter of course. The NAS report also did not suggest that EPA be required to make specific "findings" that tolerances are "**fully** protective" of infants and children. We question whether such a determination could actually be made, and fear that it will unnecessarily slow the review and approval processes without providing real, added protection, because EPA will be hesitant to certify that a tolerance is indeed "fully" protective.

Rather than first evaluating which of the NAS recommendations are already being done, which may be correct in concept but need more evaluation, whether methods exist to carry out the particular recommendations, and whether each recommendation provides added benefit or protection for the cost, EPA simply put the recommendations into legislative language. Although NACA understands EPA's desire to be responsive, blindly fixing each recommendation in legislation is dangerous because (as with the Delaney clause) it will prohibit EPA from adapting to changes in scientific understanding.

Exaggerated Exposure Assumptions. By requiring use of exaggerated exposure assumptions (100% of food contains residues at the tolerance level every day for a lifetime), EPA guarantees that its risk estimates will be vastly overstated. Although tolerances are set at the maximum use pattern (% of crop, full label rate, etc.), this does not always result in residues at the tolerance level. Thus, these exposure assumptions would negate the use of actual or average residues, which have long been agreed to by almost everyone who has dealt with this issue. The Administration's obsession with ultra-conservatism grossly overstates exposure, and makes no scientific sense.

Separate Tolerances. This bill allows EPA to establish separate tolerances for residues at any point in the food production chain. This new concept was merely alluded to in earlier testimony on the bill, and the language of the bill raises more questions than it answers. For instance, under what conditions and/or for what food forms would separate tolerances be required? Would separate tolerances be required for the same food at different stages in the distribution chain? What new or additional residue testing requirements would exist? And importantly, how will FDA conduct (and pay for) enforcement? Until these questions are

adequately debated and answered, NACA believes this provision is premature.

No Uniform National Tolerances. This legislation fails to provide for national uniformity of tolerances. Without such uniformity, the varying laws of state and local governments will place an unfair burden on agriculture, food processing and transportation industries.

Tolerances for All Inert Ingredients and Metabolites. While failing to so acknowledge in testimony, the Administration's bill will require a separate tolerance for each and every inert ingredient and metabolite in a pesticide product, regardless of toxicity. Under current law, EPA may chose to require a tolerance if the inert ingredient or metabolite presents a risk meriting such regulatory action. H.R. 4362 will require registrants to undertake massive additional testing and data development, and the data review will exhaust years of EPA staff time. By focusing scarce resources on real risk, the current system makes infinitely more sense.

Tolerance Reevaluation. This proposal requires EPA to review literally hundreds of existing tolerances and exemptions within 180 days, and identify those which do not appear to meet the new standards. To maintain an "apparently unacceptable" tolerance, registrants would be required to submit data within two years; within three years EPA must make a final decision on 75% of those tolerances, and within four years for the remaining tolerances. Tolerances and exemptions which do not meet the new standard will be revoked.

In addition to the administrative burden, it is not at all clear how this new authority will relate to the reregistration program. Since EPA is currently making similar evaluations in that context, this additional authority is redundant. NACA members have already invested approximately \$100 million dollars, and EPA has worked very hard to make reregistration a

success. Failure to coordinate these efforts would be a shameful waste of both money and time. If tolerance reevaluation is not being adequately addressed through reregistration, then the solution is to fix that process, rather than creating a rival program in mid-stream.

Further, the task which EPA proposes is enormous, the deadlines strict, and the consequences (revocation) are severe. We believe EPA's self-imposed deadlines are unrealistic. Unless EPA proposes to give the data only a cursory review, or adhere to a rigid numerical standard to determine whether a tolerance is safe, sufficient time simply does not exist to adequately analyze the data. We are also concerned that regulatory action (and "listing") will be initiated on what amounts to no more than whim. The proposed "appears to meet" standard is virtually unprecedented in its vagueness. Sufficient time will not exist in the 180 days following passage of the bill to set the standards and actually accomplish a review of all current tolerances and exemptions.

B. FIFRA AMENDMENTS (H.R. 4329)

Phase-Out/Phase-Down. Under this extraordinary new authority, EPA may restrict, reduce or eliminate the use or production of a pesticide if "credible scientific evidence indicates that use of the pesticide is reasonably likely to pose a significant risk to humans or the environment." The standard used in this section is vague, and the consequence of EPA action severe. For instance, does the "credible scientific evidence" trigger mean "some" evidence, or a preponderance of the evidence? What if that evidence was disputed by other "credible" evidence? Must "credible" evidence be peer-reviewed? These important questions are left

unanswered in the legislation.

Other definitions which are unworkably vague are "reasonably likely to pose" and "significant risk." By "reasonably likely" does EPA mean any amount greater than 50%? By "significant risk" does EPA intend something less than or more than would be required to sustain a cancellation action? NACA also is concerned that the "use" of the pesticide which leads to risk does not contemplate that phase-out/phase-down would only apply when the pesticide was not being used "in accordance with widespread and commonly recognized practice" as is currently required under FIFRA.

This authority is also redundant with both current and proposed new authorities. For instance, if EPA discovered a new risk, why would existing cancellation and/or suspension authorities not suffice? If cancellation or suspension are inadequate, why not amend them? Regarding the proposed new authorities, it is unclear when EPA would choose to proceed with a data call-in, label call-in, phase-out/phase-down, prescription use, cancellation, or suspension authorities.

In a final irony, this legislation expressly prohibits common-sense application of the phase-out/phase-down authority. This bill prohibits EPA from taking into account differences between various classes of pesticides, differences in environmental risk, and differences between agricultural and non-agricultural pesticides. At a time when the entire **production** of a pesticide could be eliminated, these considerations are extremely important. Because it ignores the significant investment of time and money which registrants make in their products, tramples the fundamental due process rights necessary to challenge unfounded government action, and denies a company the ability to legally produce basic chemicals -- possibly for other uses -- NACA

strongly opposes this provision of the bill.

Cancellation Procedures. Under H.R. 4329, FIFRA's current formal cancellation procedures would be replaced by informal rule making, a process which provides none of the procedural protection necessary to adequately defend a product's registration. Whereas the cancellation process under current law allows an adversely affected party to request an adjudicatory hearing (involving an opportunity to present testimony and cross examine witnesses before an impartial decision-maker), the informal rule making proposed here is little more than the familiar "notice and comment" process.

In the past, EPA has argued that disregarding these procedural protections is justified because the formal hearing process is "too burdensome." However, since 1980, EPA has issued approximately 40 cancellation notices under FIFRA, and a hearing with cross examination was requested in only three of those proceedings. Testimony in those hearings averaged only 21 days. Although H.R. 4329 does allow an affected party to request an informal hearing, EPA may decline to hold the hearing. If held, the hearing would not allow for cross examination or other procedures which provide important due process rights. As such, the protection offered is inadequate to a full and fair evaluation of agency action.

In addition, the burden of proof in a cancellation proceeding is inexplicably shifted from the challenger to the registrant, who must show why a cancellation should not go forward. This turns the concept of fundamental fairness on its head. Once EPA has granted a registration, having reviewed all required data, it is only fair that the party initiating a cancellation should have the burden of showing the standard for cancellation has been met.

Finally, this bill changes the standard for challenging agency action in court from whether

the action is supported by "substantial evidence" to whether the action was "arbitrary and capricious." Particularly when combined with the inability to enter testimony and examine witnesses, this change is significant. By stacking the deck entirely in favor of the agency, EPA has effectively eliminated a registrant's ability to defend its products.

To the degree data show that current procedures are inadequate or do not protect the public health, NACA has been willing to support improvements. However, the wholesale revisions contained in this bill have stripped all that is fair from the process, making a cancellation under this process a *fait accompli*. For those reasons, NACA opposes them.

Suspension by Order. Similar to the proposed cancellation language, H.R. 4329 would replace current suspension procedures with "suspension by order." In short, this proposed process eliminates the expedited hearing (including the opportunity to present evidence and examine witnesses on the record), allows EPA to proceed without simultaneously filing a notice of intent to cancel, and lowers the standard for challenging agency action from "substantial evidence" to "arbitrary and capricious."

Particularly in light of the proposed cancellation amendments, NACA questions the need for such drastic change. If cancellation is expedited, what value is there to changing suspension? Since 1972, EPA has suspended the registration of only five pesticides. One explanation why suspension may not have been used more often is that improved registration requirements, reregistration, and existing cancellation and other regulatory authorities have avoided pesticide emergencies and "imminent hazards." EPA should first be required to show how current law has failed to protect the public health, and specifically, how current suspension authority is inadequate. This is especially true, since FIFRA amendments in 1988 were designed specifically

to address weaknesses in EPA's ability to use its suspension authority. If deficiencies remain, then they should be fixed in a manner which is tailored to addressing a particular need. Rather than seeking specific improvements, the cancellation and suspension provisions offered under H.R. 4329 abandon virtually all of the concepts of fairness in current law, in favor of a process which focuses only on administrative expediency for the agency.

Label Call-In. In testimony before Congress last September (and when soliciting support for its proposal), EPA cast its label call-in proposal in terms of "relatively small changes" such as "additional warning statements." However, when reduced to legislative language, the proposal encompassed wholesale changes in labeling, packaging and even composition of a pesticide. Under H.R. 4329, EPA is authorized to order such changes if the Administrator "determines that the risks associated with the use of a pesticide can be reduced." The only limitation on EPA's authority would be if the change effectively prohibits or makes economically unfeasible substantially all use of the pesticide on one or more use sites.

The concepts of "cost" or corresponding "benefit" have not been linked to the particular risk reduction effort. (The only mention of cost is to "society" at large, which is meaningless in the context of specific agency action.) For instance, assume that EPA determines that risk could be reduced by eliminating aerial application or by a different type of formulation. Would not the cost of such changes, and the amount of benefit from the changes, be relevant considerations? By failing to include these, or some form of "least burdensome" requirement, the Administration has given itself unnecessarily broad authority and placed an unnecessary burden on registrants, users and dealers, and the public at large.

Registration Renewal ("Sunset"). H.R. 4329 recasts FIFRA's current reregistration

program as a system where pesticide registrations must be reviewed and renewed every 15 years. To accomplish this, registrations would be divided into three categories: pre-1984, post-1984, and post-amendments. Each category would have staggered deadlines for EPA to complete its review. By the deadline, EPA must let the registration expire because the application is incomplete or supported by insufficient information, renew the registration, or initiate a cancellation proceeding. If EPA fails to act within the prescribed time frame, the registration may receive an extension of one additional year. Fees paid by registrants would support this program.

While NACA understands that some type of periodic review makes common sense, we have fundamental concerns the content, structure and scope of this proposal. First and foremost, we believe that any successful review or renewal effort must be built on first completing the existing reregistration program. Once that program is complete or substantially complete, all interested parties should review the program shortcomings, to avoid repeating any of the initial program mistakes. The reregistration has already taught that (1) there must be certainty, at the beginning, on what constitutes a complete data package, (2) EPA must be realistic in the time it takes and allows the registrant to develop the required data, and (3) EPA must allow itself sufficient time and resources to analyze that data properly. This proposal learns from none of those lessons. By setting strict deadlines in legislation, without first estimating which or how much data will be required or submitted, or the time and resources necessary to review that data, EPA is setting itself up for failure and further loss of public confidence. Because of the strict, possibly unrealistic deadlines, product registrations which actually meet the existing standards will be put at unnecessary risk.

We also fail to see how this process coordinates with timetables and existing or proposed authorities regarding tolerance decisions. Without careful coordination, tolerance and registration decisions will not be consistently reviewed, resulting in wasted time, money and effort. Without careful coordination and honest evaluation of the ongoing reregistration program, this proposal threatens to disrupt public confidence, and what is universally recognized as the safest, most efficient and productive food safety and production system in the world.

Reduced Risk Pesticides. H.R. 4329 directs EPA to develop criteria for designating a pesticide as "reduced risk." Registration applications which meet the criteria would be eligible for priority review, and if other conditions are met, would receive two additional years of exclusive use of data. That this provision even exists is proof that it takes too long to bring new pesticide products to market. It is unacceptable that even simple applications can take over two years after all necessary data has been submitted. If all applications were reviewed and acted upon with reasonable speed, "priority review" would not be necessary. NACA would prefer that EPA find ways to speed the existing registration system, rather than speeding the system only as a "bonus."

On its face, this provision has certain appeal because the public wants (and EPA would be able to claim it is approving) "safer" pesticides. We ask "safer than what?" If all products registered are indeed "safe" (having submitted data and "passed" some 120 different tests required under FIFRA) this bill establishes a two tier system. Rather than increasing public confidence, this provision will actually increase public fear, because (if the program is successful) the number of "safer" pesticides will always be fewer than the "other" pesticides. Importantly, this bill also fails to recognize that once registered under FIFRA, all pesticides have shown themselves to be

"safe."

We also question whether it is truly possible to develop criteria which fairly determine which pesticide is "safer" than another. Will safety be judged to the applicator or consumer? Is one form of application "safer" than another? What about pesticides which clearly decrease the risk in one area, but arguably increase risk in another? We raise these questions because we know how difficult it will be for EPA to fairly develop criteria and administer the program. There is no question that we all want "safer" pesticides. The only question is how to develop and bring them to market. New products and technologies, and those currently "in the pipeline," prove that the market is already quickly moving in that direction. However, until we understand what standards and criteria EPA intends to use to implement this program, and until more experience is gained through EPA's current "pilot program," we believe that legislation on this subject would be premature.

Fees. In addition to the fees imposed for tolerance review and approval activities under H.R. 4362, H.R. 4329 imposes at least five new user fees. New fees are assessed for registration renewal ("sunset"), exports, new supplemental reregistration fees (except for biological pesticides and minor uses), an extension of the annual maintenance fees, and a new fee on pesticides eligible for reregistration.

NACA is sympathetic to the resource demands upon EPA. However, in spite of repeated requests for an accounting of the millions of dollars already paid to support reregistration, EPA has failed to provide any such document or report. Nevertheless, NACA member companies have continued to honor the fee structures put in place through FIFRA '88 and its amendments. It is most disturbing that there is no evidence in this legislation, or in testimony to date, that the

Administration has made even a token effort to estimate how much any of these new programs and authorities will cost. In fairness, registrants cannot be expected to come to the table with a blank check, and receive no guarantee that their investment is sufficient, or is being well managed. As new sources of revenue are discussed, industry and government alike must honestly address the cost to fully fund existing programs, the additional cost to fund new programs, and then carefully evaluate the incremental benefits derived from that added cost.

Prescription Use. For pesticides classified under the "restricted use" provisions, H.R. 4239 would allow EPA to impose a condition that the pesticide be applied only by prescription. While the goals behind the provision are worthy of discussion, NACA doubts that sufficient structures are currently in place to ensure that such a system could currently be administered fairly and effectively, and without significant disruption of agricultural practices. Adequate statutory guidance (absent in this proposal), and available and affordable commercial services are absolute prerequisites to a workable prescription use plan. At present, this proposal is at best premature.

Citizen Suits. H.R. 4329 would authorize any person (with or without a financial interest in the matter) to bring suit in Federal Court against EPA, a pesticide registrant, or any pesticide user except for certain agricultural producers engaged in production, for any alleged violation of FIFRA or any EPA pesticide regulatory requirement. However, a citizen may make a request (not subject to judicial review) that the Administrator or a State take action against a producer. Provisions exist for the payment of attorney fees, expert witness fees, and litigation costs to any party who "substantially prevails." NACA believes that this is an invitation for gridlock. We fail to see how this provision is consistent with the Administration's goals of reinventing

government, or of forging a partnership with the regulated community.

Civil and Criminal Penalties. Current civil penalties for registrants, commercial applicators and distributors of \$5,000 per violation are increased under H.R. 4329 by 500%, to \$25,000 **per day**, up to a maximum of \$400,000. Furthermore, the current warning requirement prior to imposition of a fine has been eliminated. For criminal penalties, current law provides for fines (maximum of \$25,000) and jail (maximum 1 year) for **knowing violations** by registrants, commercial applicators and distributors. H.R. 4329 not only increases the fines (to \$50,000), but also makes them **per day**, and allows for **double fines** for second violations. Jail time is also increased from 1 year to 5 years. However, by far the most troubling aspect is that the standard for any violation of FIFRA has changed from a **knowing** violation to merely a **negligent** violation.

NACA agrees that EPA should have strong, meaningful authority to punish intentional violators, as well as repeat offenders. But we question, on grounds of fundamental fairness, whether such unprecedented, stringent authority (particularly as applied to smaller, commercial applicators or dealers) is necessary to deter negligence. The proposed scheme establishes virtual strict liability, with severe penalties. We wonder if improved training and education are not better approaches to decreasing actual risk and protecting the environment. This approach is also more consistent with the Administration's goal of reducing pollution at its source. This proposal, on the other hand, is clearly designed for its punitive effect.

Inspection and Record Keeping. Under current law, EPA has authority to require pesticide producers to maintain certain records (FIFRA Sec. 8), and to inspect establishments where pesticides are held for sale or distribution (FIFRA Sec. 9). H.R. 4329 expands both

authorities, to require and inspect records of distributors, pesticide testing facilities, and commercial applicators. EPA would also have new authority to inspect pesticide user premises and pesticide testing facilities. Inspection of private residences and farms would be limited to instances of "suspected violations." In addition, EPA would have the authority to require record keeping for all agricultural pesticide use.

Of these provisions, and many others not listed, NACA is most concerned about inspection of private residences without a warrant. If a "suspected violation" is enough to initiate a search, and refusal (even on good faith grounds) to consent to a search constitutes a separate violation, it is not difficult to imagine that an anonymous complaint (whether founded or not) could lead to \$25,000 or more in penalties against a farmer who refuses to consent to a warrantless search. We believe the Administration's proposal is rife with such possibilities, and represents a dangerous incursion into the privacy and personal liberty of its citizens.

Nevertheless, NACA understands, and has no objection to the Administration's desire to encourage safe production and use of pesticide products. We believe that a system where everyone adheres to the highest level of professionalism serves the regulated community, the regulators, and the public. However, when seen in light of the new civil and criminal penalties (particularly for negligent violations), these requirements are ominous. As with the penalty provisions, a system which educates and rewards compliance would be infinitely preferable.

Exports. Under new regulations put in place during this Administration, any pesticide made in the U.S. (including unregistered pesticides) may be exported as long as it is labeled in accordance with EPA regulations and the exporter receives from the foreign purchaser a written acknowledgment of the pesticide's unregistered status. Under H.R. 4329, export of pesticides

banned for use in the U.S. would be prohibited, subject to two narrow exceptions. As we have testified repeatedly in the past (and will elaborate on if you desire), we believe that current law is working well, that these restrictions are unwarranted, and that further restrictions will drive jobs, production and research out of the United States.

Further, the proposal to raise \$4 million through a fund which amounts to an export tax for foreign technical assistance programs is simply a bad idea. To our knowledge, no other country taxes its own exports -- for any reason. Further, these programs would be largely redundant, duplicating many of the product stewardship efforts already in place and/or in development by many NACA member companies.

IV. CONCLUSION

Mr. Chairman, we sincerely wish we could tell you that this bill could easily be fixed. It cannot. By creating too many new authorities with vague and ambiguous standards and triggers, failing to coordinate with existing authority, and generally operating without adequate due process protection, NACA cannot offer its support. As we have said repeatedly in the past, NACA does stand ready to work with this committee and any other interested party. We believe that starting with H.R. 1627, a bill with the support of 220 cosponsors, offers the best possibility for real reform.

**Prepared Testimony of
Dr. Stephen Ziller, Vice President for
Science and Technology
Grocery Manufacturers of America, Inc.**

Mr. Chairman and Members of the Subcommittee, I am Dr. Stephen Ziller, Vice President for Science and Technology of the Grocery Manufacturers of America, Inc. (GMA). GMA is an 85-year old national trade association comprised of more than 130 companies which manufacture food and other products sold in retail stores throughout the United States. Member companies employ over 2.5 million people nationwide and have annual sales in excess of \$360 billion that represent more than 85 percent of the packaged food sold at retail in the United States.

GMA recognizes and greatly appreciates the long and constructive efforts of this Subcommittee and others in seeking to bring about reform of the nation's food safety laws, particularly as they related to the approval of pesticides for use of agricultural crops and the establishment of tolerances for pesticide residues that may remain on raw agricultural commodities or in processed foods. In this regard, the provisions of the Federal Food, Drug and Cosmetic Act establishing premarket approval of pesticide residues and other substances found in food were first enacted in the 1950's. The Federal Insecticide, Fungicide and Rodenticide Act, the law under which pesticides are registered, was initially passed in the 1940's and has been amended over the years. There has not been, however, a coordinated review of the two statutes' food safety provisions.

Changes in science and technology that have taken place in the ensuing years -- including advances in analytical chemistry and the science of quantitative risk assessment -- could not have been anticipated when these laws were first enacted. In addition, judicial decisions in the last few years interpreting very restrictively the authority of the

Environmental Protection Agency in this area has complicated that agency's ability to apply the law in a rational and scientifically-defensible fashion.

In short, the time has come for the nation's food safety laws to be modernized. For nearly two decades, GMA has supported efforts to do this. That support, however, has been conditioned upon the inclusion in the law of provisions that would strike an appropriate balance between preserving an abundant and wholesome food supply and protecting consumers against unsafe pesticide residues. It has been in furtherance of this fundamental objective that GMA has participated in the debate surrounding the many food safety legislative proposals that have been considered over the years.

One bill presently pending in Congress to amend both the FFD&C Act and FIFRA (H.R. 1627, introduced by Representative Lehman, and S. 1478, introduced by Senator Pryor) does this effectively, and GMA strongly supports this proposed legislation. The Administration's legislative proposal for reform of the pesticide safety provisions of the laws, on the other hand, misses the mark and has a number of fundamental flaws. It is a step backwards.

DISCUSSION

National Uniformity

Noticeably absent from the Administration's proposal is a provision that has been included in previous legislative proposals and that is increasingly recognized as essential, to ensure the consistent application of the pesticide laws throughout the United States -- a provision precluding states from issuing different tolerances, warning label requirements, or other limitations on pesticide residues in food products. As a result, states would be permitted to continue adopting different standards, whether they are imposed directly

through tolerances or indirectly through labeling requirements. Regrettably, this approach fails to take advantage of the growing body of scientific expertise at the federal level that is designed to ensure consistent application of the most advanced scientific techniques. Once the federal government has applied these testing procedures and established tolerances and other such pesticide safety limitations, they should be uniformly applied throughout the country.

Risk Standard

The proposed legislation would appropriately replace the current zero-risk Delaney Clause with a negligible risk standard for both raw and processed foods in the case of pesticides that are potential carcinogens as recommended by the National Academy of Sciences. EPA would be required, however, to use "conservative risk assessment methods" in determining that a tolerance provides a "reasonable certainty that no harm will result" from all anticipated exposures to the chemical. This standard would be needlessly burdensome and confusing and would come very close to the zero risk standard that it purports to replace. This is compounded by the requirement that the agency calculate dietary risk based on the extreme assumption that residues are at the full tolerance levels and that all of the potential foods are treated with the particular pesticide, unless the agency has adequate data demonstrating otherwise.

In the case of non-carcinogenic pesticides, the general "reasonable certainty" standard would apply, but with the additional requirement that the tolerance incorporate an "ample margin of safety" based on the exposure amount indicated not to cause adverse effects in significant subpopulations. For risks to children and infants, the proposed legislation would direct EPA to increase the normal margin of safety tenfold. We agree that the diets of infants and children do need special attention; but EPA should be encouraged to

use its appropriate regulatory discretion to examine their needs on a case-by-case basis rather than by use of an arbitrary factor.

In fact, actual residue levels in raw agricultural commodities and processed foods are substantially below the tolerances that EPA establishes for residues in raw products under current law. This occurs because the agency's exposure calculations are already based on extremely conservative assumptions about pesticide use and the extent to which processing reduces any remaining residues. Application of pesticides to food crops is performed to minimize residues at time of harvest, and post-harvest processing generally reduces those residues even further. Consistent with this approach, which has historically worked well to ensure that pesticide residues do not exceed safe levels, EPA should be permitted to continue calculating dietary exposure levels on the basis of actual data whenever possible and not be required to arbitrarily make unreasonable, extreme assumptions.

Consideration of Benefits

Pesticides are highly important to the production of food in this country. These chemicals indirectly promote public health by controlling disease and damage to food, thereby providing nutrition and affordable food for American consumers. Indeed, the National Academy of Sciences has recognized that the benefits of pesticides are an important consideration in tolerance setting.

The Administration's proposal, however, would all but eliminate the consideration of benefits derived from a pesticide's use in establishing tolerances for residues. First, the proposal would prohibit entirely the consideration of benefits in the establishment of any new residue tolerance. For an existing tolerance that does not meet the new risk standard determined by EPA, the proposal would give EPA the authority to extend the tolerance

for up to five years but only if it can pass a very stringent test; one element of this test is that the "health benefits" of the pesticide are greater than the dietary risks;" "health benefits," however, would specifically exclude benefits from "an adequate, wholesome, or economical food supply." As a practical matter, few benefits would qualify for this very narrow definition.

Because the proposal effectively eliminates benefits considerations in the pesticide approval and tolerance setting process, the availability of many pesticides crucial for the production of food crops would be jeopardized. This would be an ironic result at a time when the National Cancer Institute and virtually every other major public health organization is encouraging Americans to eat more fruits and vegetables, the very products most susceptible to plant disease and damage for which pesticides are so important.

Multiple Tolerances

The Administration's proposal would also authorize EPA to establish separate tolerances for a particular pesticide at each stage of a food's change of production or marketing, including at the point of harvest, after processing, and at the retail level. Not only does this invite administrative chaos both in terms of setting the tolerances in the first place, and especially in their enforcement, but it is contrary to a principal goal of food safety law reform. At least for processed products, there is no reason to differentiate between the permissible level of a residue on a finished food at either its point of production or sale.

Pipeline Provisions

The current law does not contain an express provision allowing treated crops to move through the system if a pesticide tolerance is modified or revoked. The legislative

proposal introduced by Representative Lehman and Senator Pryor includes such a pipeline provision that would permit the continued marketing of foods containing residues that, although rendered no longer appropriate, do not exceed the tolerance in effect at the time the pesticide was applied. The pipeline provision contained in the Administration's proposal, however, is vague and subject to misinterpretation.

A practical pipeline provision in the law will help avoid unnecessary disruptions in the food supply. Therefore, it is important that this provision clearly apply to all potentially affected products. These would include unharvested crops as well as processed foods that are made from raw agricultural commodities if the raw commodity was treated with the pesticide prior to a change in tolerance, so long as the residue on such commodity is within the prior tolerance level.

Enforcement Provisions

For the last several years, there has been considerable debate about the adequacy of EPA's and the Food and Drug Administration's authority to enforce the pesticide-related food safety provisions of the law. Typically, the agencies have argued for more powers, but have failed to demonstrate why their existing authority is not sufficient to enable them to do their job. As a result, Congress has consistently rejected the agencies demands.

The Administration's proposed legislation, purporting only to modernize the food safety laws, seeks to expand EPA and FDA enforcement authority as well, through the back door. This apparently last minute addition of non-germane provisions to this proposal unnecessarily complicates further an already complex issue. Among other things:

1. The proposal would give FDA the administrative authority to embargo and order a recall of food that the agency believes contains pesticide residues in excess of a legal

tolerance. Under current law, food manufacturers routinely withhold food from distribution voluntarily and recall products when FDA or the company itself has evidence suggesting that the product is misbranded or adulterated -- and, in the rare circumstance when a company refuses to cooperate voluntarily, FDA can obtain a court order to seize the product. In other words, FDA does not need additional embargo or recall authority and it should not be granted.

2. FDA would also be given the authority to impose substantial civil monetary penalties on companies for distributing food that contains pesticide residues in excess of established tolerances. Again, current law gives FDA ample authority to prevent the introduction into interstate commerce of adulterated products. In addition, under current law, companies and their management who violate the law can be criminally prosecuted. Civil penalties would add nothing but opportunities for abuse, plea bargaining, and expanded bureaucratic procedures.

3. EPA would be given expanded powers to enter and inspect a broad range of food processing facilities to enforce the pesticide laws; the civil penalties that EPA already has the authority to impose would be substantially increased. There has been no showing that the agency's existing inspection authorities are in any way inadequate or that the civil penalties that the agency assesses are not already substantial.

4. Private citizens would be given legal standing to bring lawsuits against companies, or even government agencies, to enforce the pesticide laws. Just imagine the rush of litigation, much of it frivolous, that food processors and the government could be forced to defend if the Administration's proposal is enacted.

5. And finally, for no apparent reason, a provision is included in the Administration's proposal that would grant special "whistle blower" protection to employees who allege violations of the pesticide laws. There is a plethora of state and federal laws that already protect employees from discharge or other discrimination in such situations. This kind of provision simply does not belong in the food safety law.

CONCLUSION

GMA is always encouraged by legislative efforts to address the antiquated provisions of the nation's food safety laws. The food industry is committed to ensuring that its products are safe and wholesome. Because of advances in science and technology during the nearly 40 years since the pesticide residues and related provisions of the law were first enacted, it is time for the law to be brought up to date. After so many years of debate, a consensus has emerged. The Administration's plan represents an onerous step in the wrong direction.

GMA looks forward to continuing to work with the Congress in the development of sound food safety policy. Thank you for this opportunity to participate in today's proceeding.

STATEMENT OF

WILLIAM D. GULLICKSON, JR.
CHAIRMAN, CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION

Introduction

I am Bill Gullickson, Jr., President of McLaughlin Gormley King Company (MGK) in Minneapolis, Minnesota. Today, I am here in my capacity as Chairman of the Board of Directors of the Chemical Producers and Distributors Association (CPDA). Accompanying me is Warren E. Stickle, President of CPDA. We are delighted to have the opportunity to appear before members of the House Subcommittee on Department Operations and Nutrition to discuss the Administration's pesticide legislation as well as a number of related issues of importance to our association.

By way of introduction, CPDA is a voluntary, non-profit membership association consisting of about 90 member companies engaged in the manufacture, formulation, distribution and sale of some \$3.5 billion worth of products used on food, feed and fiber crops, and for lawn, garden and turf care.

Before we share with members of this Subcommittee our thoughts regarding H.R. 4329 and H.R. 4362, we would first like to commend you, Mr. Chairman, for moving forward with hearings on this legislation. We look to your leadership to bring together the many divergent views regarding the regulation of pesticides in reaching a fair and reasonable consensus on FIFRA.

We will first turn to H.R. 4329, the Administration's legislation to amend FIFRA. We at CPDA have a number of concerns with this legislation and today we will offer our thoughts on how this legislation could have a severe impact on CPDA members -- many of whom are small to medium-sized companies. In discussing the many changes proposed in the Administration's bill to amend FIFRA, we will also share with the Subcommittee some alternative proposals developed by CPDA which, we believe, will accomplish the common goal shared by all -- namely, the preservation of the integrity of our nation's food supply and the increased efficiency and improvement of EPA's pesticide programs.

Our other comments will focus on H.R. 4362, the Administration's bill to amend the Federal Food, Drug & Cosmetic Act (FFDCA). CPDA's testimony will address the concept of negligible risk in setting tolerances for pesticide residues in foods and we will examine related food safety issues which include the national uniformity of tolerances and inerts. Again, we thank you for the opportunity to be here today.

I. Pesticide Regulation Under FIFRA

Phase-Out/Phase-Down

CPDA is strongly opposed to the provisions contained in H.R. 4329 which would allow the EPA Administrator to phase-out or phase-down the use or production of a pesticide if scientific evidence indicates that its use is "reasonably likely to pose a significant risk to humans or the environment."

First, we at CPDA believe that other safeguards in FIFRA exist which allow the Administrator to address potentially harmful chemicals. For example, current FIFRA already allows the Administrator the authority to place certain restrictions on the use of a pesticide as a condition of its registration. Second, we believe that the improvement of the present cancellation procedures so as to provide a more expedient method for removing bad actors from the marketplace would obviate the need for any provisions calling for a phase-out or phase-down of the use and production of a chemical for which EPA has concerns pertaining to its safety.

Third, the Administration's phase-out/phase-down provisions are based on a comparatively lenient standard that a chemical is "reasonably likely" to pose a "significant" risk to humans or the environment. We at CPDA do not believe that it is prudent to proceed with a regulatory action against a chemical which could have a serious adverse impact on growers and other end-users simply on the premise that a product is "reasonably likely" to pose a "significant" risk. Rather than a regulatory standard based on "significant" risk, it should be an "unreasonable" risk. The grave consequences that would result from eliminating or capping the production of a pesticide necessitates that a higher degree of certainty relating to any risk associated with use of that pesticide be adopted. The standard contained in the Administration's bill could be abused by those who would advocate a total ban of all pesticides and lead to a modern day witch hunt targeting hundreds of necessary and beneficial products which have been in common use for years without resulting in any harm to man or the environment.

Fourth, the Clinton phase-out/phase-down proposal erroneously equates the elimination of pesticide use with a reduction in risk. Science has clearly demonstrated that such a correlation cannot be made. The curtailment or elimination of a pesticide product from the marketplace could have an adverse impact on a farmer's ability to exercise Integrated Pest Management (IPM). The success of IPM is dependant, in part, on a wide range of pest control tools being made available to the farmer. The disappearance of one product from the farmer's arsenal could actually result in a shift in use patterns to other products which may pose an even greater potential risk.

Finally, we at CPDA believe that careful consideration must be given to the potential economic impacts which would occur if production caps were to be placed on pesticides marketed primarily for export. By far, the regulatory standards of the United States are much stricter than those of many of our global trading partners. The higher cost basis for U.S. producers who must incur significant capital expenditures to comply with stringent federal regulatory standards already places domestic manufacturers at somewhat of an economic disadvantage compared to their foreign competitors. We at CPDA believe that it would be unwise to adopt legislation calling for caps on American production which could further erode the position of domestic pesticide manufacturers in the global markets. Such legislative provisions would place American jobs in serious jeopardy at a time when the U.S. is seeking to strengthen its economy.

Fees

We at CPDA are adamantly opposed to the creation of any additional pesticide fee authorities at this time. CPDA members believe that it is premature to create additional fees when the Agency has not yet provided a detailed cost accounting of how and where the monies collected in the reregistration program have been spent.

In the last three years, the EPA has maintained that its reregistration program is experiencing a shortfall of revenues. Three years ago, this deficit was estimated at \$160 million, then \$100 million, and then \$40, \$35 and \$32 million. Appearing before a joint House-Senate Congressional committee hearing on September 22, 1993, Administration officials estimated that the current reregistration shortfall was \$20-million. Now, however, it would appear that the fee provisions in H.R. 4329 are calculated to generate in excess of \$60 million in additional fees. CPDA asks that the Subcommittee take a closer look at the numbers.

First, H.R. 4329 provides for a two-year extension of EPA authority to levy maintenance fees through September 30, 1999. We would like to point out to this Subcommittee that back in the fall of 1991, CPDA and four other industry trade groups negotiated a compromise on maintenance fees with EPA. This compromise was ultimately adopted as part of the technical corrections package amendment to the 1990 Farm Bill which was signed into law by President Bush.

The compromise package included provisions which:

- o adjust the cap for the first 50 products from \$20,000 to \$55,000, and increase the cap for products 51 or more to \$95,000;

- o maintain the fee at \$650 for the first product, and \$1,300 for each additional product up to the adjusted caps;
- o establish a small business cap at \$38,500 for the first 50 products, and \$66,500 for products 51 or more. A small business registrant is a corporation, partnership, or unincorporated business that has 150 or fewer employees and during the last 3-year period had an average annual gross revenue from chemical sales that did not exceed \$40,000,000;
- o beginning in 1992 and continuing through 1997, adjust the payment timetable from March 1 to January 15, thus allowing the Agency to collect funds earlier to mitigate its existing cash flow problems;
- o allocate one-seventh of the maintenance fees collected by EPA in 1992, 1993 and 1994, and in 1995, 1996 and 1997 up to \$2 million annually to accelerate reregistration (Fast Track) and expedited processing of funds.

This amendment package raised \$15.1 million thus fulfilling its statutory requirements included in the 1988 FIFRA amendments. In fact, it created a surplus of at least \$1.1 million beyond the \$14 million required under FIFRA. As such, a two-year extension of maintenance fee authority, as proposed by H.R. 4329 can be expected to generate an additional \$30.2 million (i.e., \$15.1 million/year x 2 years).

Second, H.R. 4329 calls for a \$120,000 supplemental reregistration fee on an active ingredient registered for a major food or feed use and a \$60,000 supplemental reregistration fee for active ingredients registered for non-agricultural uses. If two or more registrants are required to pay the supplemental reregistration fee, the fee would be apportioned among the registrants on the basis of U.S. sales of the active ingredient during 1990-1992. The active ingredient fees set forth in H.R. 4329 represent levels which stand at about 80% of the fees adopted by Congress in enacting FIFRA "Lite" in 1988. If one considers that in 1989, EPA collected some \$35 million in active ingredient fees as a result of the fee levels established by FIFRA Lite, we can expect to collect some \$28.0 million, or 80% of the 1989 levels, under the adjusted active ingredient fees proposed under H.R. 4329.

Third, the Administration's legislation calls for a \$750 per product reregistration fee which would apply to all products deemed eligible for reregistration. H.R. 4329 would be given the authority to adjust this fee to a level that would generate at least \$4,000,000 during the four-year period following enactment of the legislation.

Below is a summary of the total revenues that can be expected if the three fee authorities detailed in Section 11 of H.R. 4329 were to be adopted:

- A two-year extension on maintenance fees: \$15.1 million/year x 2 years = \$30.2 million
- A \$750 reregistration fee per product = \$ 4.0 million
- AI: \$120,000 (food uses) \$28.0 million
 AI: \$ 60,000 (non-food uses) = _____
 (80% of \$35 million collected in 1989!)
 Total: \$62.2 million

The \$62.2 million as calculated above, far exceeds the \$20 million shortfall stated by EPA officials in testimony presented to Congress last September.

The lack of consistency in EPA's funding estimates illustrates the strong need for a full and complete explanation of expenditures for the registration and reregistration programs, including Fast Track expenditures. We at CPDA believe that Congress should require EPA to provide a clear and detailed accounting of where and how the monies have been spent since the reregistration program was created under the 1988 FIFRA amendments. It is only when we obtain a full accounting of the program that we can then come up with an accurate cost of the reregistration program and a definite assessment of the shortfall.

In testimony presented before this Subcommittee last year, Ralph Engel, President of the Chemical Specialties Manufacturers Association (CSMA), recommended that a provision be written into FIFRA which would require EPA to contract with appropriate outside management personnel to conduct a thorough examination of the registration and reregistration process and to make recommendations in a report to Congress as to how to specifically improve program performance and meet the 1997 statutory deadline. CPDA agrees with CSMA and would support the initiation of an outside, independent review of OPP prior to any determination regarding a new request for additional fees.

Like all other federal agencies, EPA is attempting to "reinvent" government by seeking ways to streamline its operations to do more with less resources, thus creating a more effective and efficient process. As described more fully elsewhere in this testimony, CPDA has been working with EPA in developing several specific proposals which, we believe, will streamline OPP activities by improving certain efficiencies and eliminating the unnecessary waste of limited Agency resources, both financial and manpower. We at CPDA are pleased to inform the Subcommittee that the Agency has responded in a very positive manner to many of our recommendations and has expressed a willingness to implement some

of our suggestions. Moreover, EPA officials have indicated that some of these changes could be put in place in as short a time frame as four to six months. Among the CPDA recommendations which EPA is now considering include the feasibility of allowing simple registration amendments to be made through notification and improvements in the process for review of acute toxicity data. The changes now under consideration would reduce the employee to manager ratio from its current level of 6 to 1 down to 11 to 1. We at CPDA believe that the results of this streamlining process should be evaluated before determining the necessity for any additional EPA resources.

CPDA does not believe that an extension of maintenance fees to 1999 should be considered until we move closer to these dates and have had the opportunity to see what impact the various streamlining reforms have had on OPP activities. It is premature to address the continuation of maintenance fees at this time. There will be additional FIFRA reauthorizations prior to 1998 at which time this issue can be revisited if Congress deems it necessary. Moreover, although the EPA seeks an extension of maintenance fees for 1998 and 1999, it does not seek an extension of the prohibition of registration fees for the same time frame. Thus, under the present EPA proposal, registrants would have to pay both extended maintenance fees and new registration fees.

CPDA remains committed to fulfilling its current statutory obligation of raising \$14 million a year to fund the reregistration program through September 30, 1997 as provided by FIFRA. However, we strongly believe it is premature to enhance EPA's fee authority until we have had a full review of how and where EPA has allocated industry fees already collected, and until we assess the impact of the Agency's present OPP streamlining initiatives.

Rather than the creation of additional fees, the immediate focus of FIFRA should be on streamlining the reregistration program, improving efficiencies, and eliminating waste and duplication.

Citizen Suits

CPDA opposes the provisions in H.R. 4329 which would allow a private individual to file civil suit against EPA for failure to enforce the requirements of FIFRA. We at CPDA believe that a citizen suit provision in FIFRA could lead to a proliferation of frivolous lawsuits brought by every activist group seeking the total elimination of pesticides. A provision allowing for citizen suits under FIFRA would keep EPA firmly ensconced in court proceedings and would consume a significant share of Agency resources which would go toward legal and court fees. CPDA does not believe that this is an appropriate use of limited Agency funds and manpower.

Registration Sunset

CPDA is opposed to the registration sunset provision contained in H.R. 4329. This provision would require that active ingredients be reviewed periodically to ensure that they are in conformity with scientific standards. If EPA determines that the pesticide does not meet all applicable requirements, the Agency would be required to initiate cancellation proceedings. We at CPDA believe that this provision would create an unnecessary burden for the Agency and the industry alike. We agree that it is important to address any questions pertaining to the safety and efficacy of registered chemicals as these questions arise. However, we do not believe that it makes sense to engage in a wholesale review of every registered chemical. Much of the information we have on chemicals and the scientific testing methodologies will not change within the relatively short time frames set forth in the Administration's proposal. If EPA has a specific concern pertaining to a chemical, the Agency already has the authority under the data call-in provisions of FIFRA Section 3(c)(2)(B) to request the appropriate testing. It is a waste of limited resources to require the resubmission of scientific data which will provide little if any additional new information.

CPDA opposes the registration sunset provisions as presently drafted in H.R. 4329. We do not believe that it makes sense to engage in the wholesale review of every currently registered chemical. The provisions in the Administration's bill would place the enormous burden on registrants to submit potentially vast amounts of data to the Agency, much of which might have, at best, marginal value. While future technology promises to provide the tools to generate ever increasing amounts of information, some of this "new" data may not represent a significant change from what we already know about a chemical today.

CPDA recognizes that as science evolves and technology allows for testing at higher levels of sensitivity, so will certain data requirements to support pesticide registrations change over time. To this end, some of the information necessary to maintain pesticide registrations should be updated periodically. However, it is unnecessary to duplicate data which is scientifically valid. Once a pesticide has passed the rigorous requirements of the present reregistration program and the Agency has obtained a complete set of scientifically valid data on a particular product, it is unnecessary to generate a repeat battery of tests to obtain information which has already been accepted and approved by EPA. Instead, further data requirements should focus on specific and significant toxicological concerns over a pesticide should they arise in the future. As such, EPA and industry resources can be more effectively utilized by focusing on specific concerns based on significant evidence of a chemical's possible unreasonable adverse effect on man or the environment.

When the DORFA Subcommittee took up H.R. 3742 (the Rose bill) during the 102nd Congress, it considered a similar provision which would have called upon EPA to perform a "periodic update" of information to support pesticide registrations. At the time, CPDA endorsed a substitute proposal which would have required EPA to review pesticide registrations and to utilize its existing data call-in authority under FIFRA Section 3(c)(2)(B) to obtain information deemed necessary for continued support of pesticide registration. The proposal also gave EPA a second option of publishing an order in the Federal Register which would have identified specific data requirements and would have described the significant evidence of unreasonable adverse effects to human health or the environment upon which EPA was basing its request for data. We understand that the intent of the Administration's "sunset" provision is to avoid the type of logjam that has occurred with today's reregistration program. CPDA believes that this can be achieved through such an alternative mechanism, as described above, which safeguards against the unnecessary duplication of data.

Cancellation

We at CPDA applaud the Administration for including a discussion of benefits in its recommendations to revise current cancellation procedures under FIFRA. Specifically, H.R. 4329 contains a requirement that EPA consider the potential impact of the proposed cancellation action on consumers, retail food prices, production of agricultural commodities, and the agricultural economy. Dr. John D. Graham, Director of Harvard University's Center for Risk Analysis, discussed the importance of benefits during his testimony presented before this subcommittee on July 14, 1993. "If farmers are suddenly unable to use pesticides," he stated, "their crop yields (per acre) may decline due to insufficient pest control. Since the costs of producing the same level of output would then be higher, farmers would be forced to charge higher prices for the crops they produce."

"The benefits of lower food prices are not simply financial," said Graham. "[T]hey impact the health of parents and their children. For example, if higher prices for fruits and vegetables cause dietary habits to shift away from these foods, an increase in the risk of cancer, heart disease, and other diet-related diseases can be expected. This outcome is more likely among low-income populations, where price sensitivity is highest and knowledge of the health effects of poor nutrition may be lower."

Dr. Graham further testified that "...In some situations, the loss of a pesticide may cause direct harm to public health as a result of consumer exposure to the fungi that thrive without the pesticide. For example, although many fungicides have been shown to cause cancer in animals at high doses, some of the toxins

produced by fungi, such as aflatoxin, are also known to cause cancer. One of the benefits of pesticides is the human health protection resulting from the destruction of fungi."

CPDA shares the sentiments conveyed by Dr. Graham. We believe that any changes to the current cancellation procedures must take into consideration the health and nutritional benefits to be derived from the use of pesticides. We are pleased that the Administration has seen fit to include this important provision requiring EPA to consider the benefits of pesticide use before proceeding with a proposed cancellation.

We at CPDA are also pleased that the Administration has included in its bill a process whereby EPA would be required to consult with the Secretary of Agriculture before proposing the cancellation of an agricultural use pesticide, and the Secretary of Health & Human Services before initiating cancellation proceedings on a pesticide registered for public health uses. CPDA also supports the directive contained in H.R. 4329 which would require EPA to consider changing the classification of a pesticide from general to restricted use as an alternative to cancellation.

Without question, CPDA agrees with the Administration that the current cancellation procedures should be streamlined and simplified so as to allow the Agency to move quickly to remove "bad actors" from the marketplace. The experience of the last fifteen years has clearly demonstrated that the cancellation process has taken too long, with some products taking more than a decade to remove from the marketplace. However, we feel that in revising the cancellation provisions of FIFRA, caution must be taken to fully protect the due process rights of the registrant and end users who depend on the availability of the chemical in question.

The Administration's H.R. 4329 would replace the current formal adjudicatory hearing process with a notice-and-comment cancellation process which includes an informal hearing. A registrant would have to request an informal hearing within 21 days of publication of a proposed cancellation order in the Federal Register. Comments on the proposed action would have to be submitted to the Agency within 90 days of publication in the Federal Register. In the absence of a procedure which would provide for an advance notice of proposed rulemaking to be issued prior to a notice of proposed rulemaking, we at CPDA believe that the short time periods set forth in the Administration's legislation are inadequate. Under H.R. 4329, registrants, end-users and other interested parties would have only one opportunity to examine the complex issues inherent in any cancellation action. As such, we would like to suggest longer time periods during which interested parties could request an informal hearing and/or submit comments regarding a proposed cancellation.

Moreover, H.R. 4329 would allow the EPA Administrator to deny a registrant's request for an informal hearing if "holding a hearing would not be in the public interest." We at CPDA are concerned that the inclusion of such legislative language could deny a registrant of his due process rights to hear arguments on all sides as they relate to the proposed cancellation of a pesticide. It is imperative that any revisions to the cancellation procedures under FIFRA preserve a mechanism which protects the right of a registrant to defend his product and to present supporting scientific evidence.

While we support the Administration's goal of expediting and simplifying current cancellation procedures, we believe that the cancellation provisions of H.R. 1627, the Lehman-Bliley-Rowland food safety bill introduced earlier this year, provide a better alternative for achieving this same objective. Like the Administration's proposal, H.R. 1627 would eliminate the current formal adjudicatory hearing requirement for cancellation of pesticide registrations. It would also provide for consultation between EPA, USDA and HHS.

However, unlike the Administration's bill, H.R. 1627 provides for scientific committee peer review of the evidence supporting proposed cancellation, pre-cancellation notice to pesticide registrants that includes a summary of the validated test or other significant evidence upon which the Administrator proposes its action, an advance notice of proposed rulemaking (to be followed by a notice of proposed rulemaking), and the right to seek judicial review of a final cancellation order. CPDA strongly supports all of these provisions contained in H.R. 1627. In addition, CPDA believes that it is critically important that registrants be given an opportunity to cross-examine witnesses in any informal hearing adopted as part of the cancellation process so as to build a complete hearing record. In short, we at CPDA feel that H.R. 1627 provides better protection of a registrant's due process rights.

Suspension

CPDA is opposed to the suspension provisions contained in H.R. 4329. The Administration's bill seeks to decouple suspension from cancellation procedures. H.R. 4329 would allow a suspension order to remain in effect for a period of 180 days during which time the EPA Administrator could proceed with initiation of cancellation proceedings. The suspension order would automatically terminate at the end of 180 days if the Administrator does not move forward with a proposed cancellation action. CPDA does not believe that the current suspension provisions of FIFRA need to be revised at this time. Suspension, even if temporary, or for a short time, without an opportunity for a public hearing or a fact-based decision-making process, would effectively destroy the product and its public credibility. In the absence of the initiation of a proposed

cancellation action, the 180 day suspension period set forth in H.R. 4329 is tantamount to placing a chemical in limbo. This provision would merely serve to unnecessarily undermine public confidence in the safety of America's food supply and it would generate misgivings concerning the integrity of EPA's regulatory framework.

CPDA does not believe that EPA's cancellation and suspension authorities should be de-linked. As CPDA stated in testimony delivered before the House Subcommittee on Department Operations and Nutrition on March 19, 1992, "An 'easier' suspension authority would subvert the cancellation process by encouraging EPA to use the 'path of least resistance.'"

Suspension authority is an emergency procedure, established under FIFRA, which allows EPA to suspend a product deemed to pose an "imminent hazard" during cancellation proceedings. Current law requires that the Agency issue a proposed cancellation notice before or at the same time it issues a suspension order. This process ensures that suspension actions will not be taken too hastily before the full body of scientific evidence is completely evaluated.

The Clinton proposal to decouple the two authorities could result in the potential misuse of EPA's suspension authority and undermine the science-based cancellation process. We believe that FIFRA reform efforts should focus instead on streamlining the sometimes long and protracted cancellation process, thus ensuring that problem chemicals are removed from the marketplace in an expeditious manner. CPDA believes that the cancellation provisions of H.R. 1627, the Lehman-Bliley-Rowland bill, can accomplish this objective.

Label Call-In and Label Changes

While CPDA supports efforts to streamline EPA mandated label revisions, we have serious concerns pertaining to the Label Call-in provisions of the Administration's bill. Specifically, we strongly oppose the creation of new suspension and recall authorities which would allow the EPA Administrator to take action against any pesticide distributed or sold in violation of the requirements promulgated pursuant to the label call-in provisions of the bill.

Under current FIFRA, only those pesticides that are suspended and cancelled can be made subject to a mandatory EPA recall. The language in H.R. 4329, however, would expand the scope of products which could be subject to a mandatory recall to virtually any pesticide with a label violation -- no matter how minor the transgression. A product which bears incorrect labeling through perhaps an unintentional oversight on the part of the registrant certainly cannot be made subject to the same penalties as that

which apply to a product suspended and cancelled because of health or safety concerns. As such, we strongly urge members of the Subcommittee to reject any legislative language providing for mandatory recall of products under any legislation which seeks to revise EPA labeling procedures.

Similarly, CPDA believes that the label call-in provisions of the Administration's bill would significantly relax the circumstances under which the EPA could initiate suspension proceedings. Present FIFRA allows the Agency to issue a suspension notice only if EPA deems that a product poses an "imminent hazard." Again, the Administration's legislation makes it much easier for the EPA to suspend a product by removing the criteria that a product poses an "imminent hazard." As with the recall authority contained in H.R. 4329, the new suspension powers could be used against a number of products for relatively minor, inadvertent label violations. We at CPDA oppose any efforts to weaken the criteria under which EPA is allowed to proceed with a suspension action.

As mentioned earlier in our testimony, CPDA supports the Administration's goal of streamlining label changes and establishing uniform label compliance dates. In particular, CPDA applauds the Administration for proposing that one annual date -- October 1st -- be designated as the date by which registrants must comply with simple mandated label changes aimed at reducing the potential risk associated with the use of a pesticide.

We at CPDA would like to see this proposal broadened to also stipulate that one office within EPA be established to coordinate all mandated label changes for pesticide products. Many different offices and programs within EPA's Office of Pesticide Programs (OPP) require, at different times, changes on a pesticide product's label. Some of these EPA mandated changes might be to change an ingredient, an inert, or a use. Sometimes a label might need to reflect some new set of directions or warnings about use or specific health and safety instructions. Sometimes the Agency may require that the registrant reshape the label or reduce its size, or place new instructions for proper disposal of the container on the label.

Specific programs also address specific needs to change the label, such as the Endangered Species Program, container rinsing proposals from the new FIFRA "Lite" requirements, and other programs. In addition, label changes may be requested from the Air and Water Divisions of EPA to conform with the Clean Air and Water Acts. Many different offices and programs require the registrant to make changes on the label, but no one part of the Agency coordinates appropriate label changes. These various programs do not know what the other parts of the Agency are doing about label changes.

A company frequently makes a label change in response to an EPA office's request, and prints thousands of new labels, only to find that another EPA office, program or division is requiring additional changes. Many companies print up new labels just in time to throw them in the trash. It can be an expensive, time-consuming and frustrating experience and means money and jobs for many small businesses who are fighting to compete in a tough market.

To give you some idea of the magnitude of this problem, a random sampling of CPDA companies indicates that, on average, they spent in excess of \$808,600 over the past six years on labels which were ultimately discarded. For these companies, this translates to approximately 5,600 wasted man-hours and represented more than 1,613,000 labels which never saw the light of day. When one extrapolates these figures to the entire industry, it becomes very apparent that a problem exists which needs to be addressed quickly.

A number of CPDA member companies cite a definite lack of coordination between product managers, Label Improvement Program (LIP) personnel, and other Agency staff in formulating label requirements. Representatives of one CPDA member company, for example, report that they have been required to write the Confidential Statement of Formula (CSF) for the same pesticide in different ways for different EPA personnel. This same company also notes that it has received conflicting instructions from various Agency personnel regarding the wording of the Precautionary Statements found on phenoxy labeling.

Other OPP programs which affect reregistration, the container disposal program, the regulation of inerts, farm worker protection standards, certification and training requirements, and product reclassification will certainly have an impact on the fate of present labels or the re-labeling of existing stocks.

One small-sized formulator of lawn and garden products responds that it seeks to reduce waste in its labeling operations by printing small quantities of labels on a more frequent basis. However, the company also notes that it is then faced with the disadvantage of having to pay a significantly higher unit cost per label. In these troubled economic times, a small business cannot afford to incur such needless and unnecessary costs.

In an effort to improve the way in which the Agency handles label revisions, we at CPDA suggest that one office in OPP, within the Registration Department, should coordinate all label changes from all programs, all product managers, and all divisions so that there is no confusion about the necessary changes needed to comply with EPA's mandates. At present, many different offices and programs require the registrant to make changes on the label, but no one part of the Agency coordinates appropriate label changes.

Second, one date each year should be selected for all EPA-mandated label changes. We support October 1st, the date set forth in H.R. 4329, as a good date because it represents the end of the growing season as well as the beginning of a new fiscal year. All label changes could be effective on this date, so that companies can start production in the fourth quarter for the following Spring's use.

Third, companies need enough lead time to implement the Agency's requirements for both new product labeling and for the re-labeling of existing stocks. We support the time frames set forth in H.R. 4329 under which products sold or distributed by the registrant would be required to bear revised labeling on the first compliance date occurring more than one year after issuance of the proposed revisions. Products held by persons other than the registrants would have an additional two years.

The Agency has already taken steps to improve its labeling process by assembling a team of six staffers to work on label improvement. CPDA would like to recommend that this process be taken one step further and that Congress adopt legislation to establish a formal office to handle labeling streamlining so that EPA receives the appropriate funding and resources to effectively implement a label improvement program.

Reduced Risk Pesticides

We at CPDA support efforts to promote the safe use of pesticides. However, we have several concerns pertaining to the Administration's legislation which would establish a 180-day priority review of pesticide registrations deemed "reduced risk." Specifically, we believe that EPA's already limited resources would be severely strained under the registration priority schedule set forth in H.R. 4329. The registration of many effective and beneficial products would be delayed if EPA resources were to be focused primarily on chemicals meeting the criteria of "reduced risk." The registration of specialized, niche-oriented minor use pesticides could suffer the most. The economics of developing low volume minor uses is already cost prohibitive due to expensive testing requirements. It takes about \$50 million and five to ten years to bring a pesticide product onto the market. Delays in the registration of minor use pesticides in deference to so-called "reduced risk" chemicals would further erode the profitability of many minor uses and take away any incentive to develop these chemicals.

Moreover, we at CPDA believe that the designation of a new product as a "reduced risk" pesticide could misguide the public's perception of older chemicals, many of which have been used for years without significant harm to man or the environment. EPA's role is to ensure that all pesticide registrations meet the same

standard under current FIFRA of posing no unreasonable adverse effects to human health or the environment. If EPA is allowed to make a public judgement that one chemical is safer than another, the Agency would indirectly play a role in influencing marketplace trends. We at CPDA do not believe that EPA should be involved in shaping the market by favoring one product over another.

Many older pesticides should qualify for designation as reduced risk pesticides. Some products are being developed that significantly reduce the use of active ingredient, with reduction of 25 to 50 percent. Some products shift to new delivery systems, while others change their packaging to reduce exposure. Products in water soluble bags reduce exposure to handlers and applicators. Each of these types of "old" chemicals actually reduces risk and should be considered "reduced risk pesticides."

In addition, the elimination of older pesticides from the marketplace could have a negative impact on Integrated Pest Management as farmers are left with fewer tools to combat pests effectively. A broad, diverse product line which includes the continued availability of older chemicals must be preserved so that farmers may engage in IPM practices as a means of preventing the build-up of resistance to pesticides.

Exports

We at CPDA do not believe that the laws governing the export of pesticides needs to be changed at this time. Indeed, at a time when the U.S. is seeking to promote its trading status in the global markets, the implementation of unnecessary export restrictions could have a negative impact on American jobs.

While we support the Administration's goals of ensuring that chemicals banned for health or safety reasons do not make their way onto foods imported into the U.S. from foreign countries, CPDA believes that the Agency has already embarked on a number of initiatives aimed at improving the regulation of pesticide exports. For example, the EPA is working with OECD member countries on several pilot projects aimed at achieving uniformity in international pesticide regulation. In addition, on January 1, 1992, the Food and Agricultural Organization (FAO) and United Nations Environment Programme (UNEP) jointly implemented the international program on Prior Informed Consent (PIC). The PIC program embraces many of the concepts set forth in the export provisions of H.R. 4329 by allowing participating nations to receive information about pesticide exports that have been banned domestically for health or safety reasons. Participating nations would have the opportunity to prohibit these chemicals from moving across their borders.

In other activities, the United States has negotiated a set of sanitary and phytosanitary standards under NAFTA and the Uruguay Round trade discussion aimed at protecting the integrity of foodstuffs entering our country. The focus of these talks has been to harmonize standards, facilitate compliance, and eliminate any unnecessary non-tariff barriers to trade.

In the last three years, considerable progress has been made concerning the increased regulation of pesticide exports. We at CPDA oppose the inclusion of Section 3 of H.R. 4329, and request that it be deleted.

Section 3(b)(4) states that "no person may export a pesticide to a foreign country if any ingredient of the pesticide has not been and is not the subject of any registrations under section 3..." We interpret this language to mean that unregistered pesticides can be exported as long as the active ingredient and/or end use product has been registered by another entity. For example, company A registers product Y and sells it in the U.S. and abroad. Formulator B buys product Y from company A, but only exports the product (not for use in the United States). Consequently, unregistered products should not be labeled as unsafe pesticides.

There are numerous reasons why a product may not be registered with EPA. These include, but are not limited to:

- The producer does not want to subject himself to current FIFRA data compensation liabilities. With the threat of millions of dollars in data compensation payments, many would-be competitors back away from the U.S. market.
- The producer is concerned with the current wave of product liability litigation in the U.S. and does not want to fall victim to potential lawsuit.
- The producer does not feel the costs involved in generating EPA data can be justified by potential U.S. sales.
- Many foreign pesticide manufacturers have made arrangements with large multi-national firms to compete in the U.S. market. Thus, they will not allow their products to be registered in the United States and will only sell manufacturer goods which are to be formulated and exported.
- Different analytical methods used by countries in measuring active ingredients.
- Crops are not grown in the United States or the particular pests do not exist domestically.

Thus, this legislation could have great impact on many companies. For example, one of our companies sells natural pyrethrins in the United States and Canada, via an EPA registered pesticide, according to an EPA accepted AOAC method of analysis. These products can be sold in the U.S. and Canada because they conform to standards accepted in these countries, but cannot be sold anywhere else in the world with an EPA registration, its EPA label or its AOAC method of analysis. The exact same product, with the identical six esters, is not analytically measured by the same standard. The rest of the world abides by the analytical method developed and approved by the Pyrethrin Board of Kenya (PBK). The internationally accepted PBK creates a differential of 10 percent in favor of PBK. For example, a 100% concentration in the U.S. might be 10 ounces, but the identical concentrate in Kenya would be recorded as 11 ounces. A standard 20% pyrethrin extract measures 22.11% in Kenya, despite the fact that they are an identical product.

For sixty years, a conflict over analytical measurement has existed between the United States and Kenya, and for almost thirty-five years, this company has exported a pyrethrin product, identical to its U.S. counterpart, to the rest of the world with a label approved and accepted by PBK and the world.

Because of the differences in analytical methods, these products are NOT registered in the United States or Canada. Provisions of H.R. 4329, requiring the export of only EPA registered pesticides, would prevent the sale of these products overseas. If the company could not export these products, we feel confident that other companies in the United Kingdom, France, West Germany and Australia would immediately step forward to fill the void, further reducing American export opportunities.

To register this identical pyrethrin product in the U.S., according to EPA's accepted AOAC analytical methods, the concentrations would have to be labeled 22.11% concentrate (not 20%). Since there would be a perceived "difference" in concentration, the EPA would probably treat this product as a "new" product, requiring a complete set of data based on the testing of this concentrate. It would not be a "me-too" registration. Consequently, it could take between two and three years or more to register this "new" product, during which time period the product could not be sold on the international market. The cost of this registration effort, with product chemistry testing, and other testing, could run between \$75,000 to \$100,000.

Although H.R. 4329 supposedly is designed for agricultural uses (i.e., food, feed or fiber crops), it groups all pesticides together, including non-agricultural products such as sanitizers, disinfectants, cleaners, etc. Any pesticide export section, by definition, should be restricted to agricultural food uses such as those products used on food, feed or fiber crops.

We at CPDA strongly oppose the establishment of "fees on pesticide registrants" for the purpose of covering the costs of this EPA program.

First, at a time when, as a nation, we are attempting to create more jobs here at home, while stimulating exports abroad, it is ludicrous to tax our own exports, thereby driving up their costs and making them less desirable.

Second, the legislation gives the Agency the power "to assess fees on pesticide registrants." Thus, it broadly applies to ALL registrants, including those that don't export. Why should a small American formulator who does not export be forced to subsidize the exports of a larger, international company that is exporting? It is unfair to subject any company that does not export pesticides to the same fees that apply to those companies that do export.

Finally, we do not support the creation of a \$4 million technical assistance program. If the Agency is looking for a home for \$4 million, it can "reinvest" it in the registration or reregistration program.

II. The Administration's Amendments to the Federal Food, Drug & Cosmetic Act

On May 5, 1994, Congressman Henry Waxman (D-CA) introduced H.R. 4362, the Pesticide Reform Act of 1994, as part of the Clinton Administration's key proposals to amend the Federal Food, Drug & Cosmetic Act (FFDCA). This legislation raises many concerns by: 1) creating unnecessary and duplicative EPA regulations; 2) stimulating significant additional costs; 3) increasing the burden on Agency resources; 4) creating a "new" Delaney Clause; 5) delaying the reregistration process by superimposing a new tolerance review process; 6) encouraging the worst case assumptions on exposure data and pesticide residues on food; and, 7) containing no uniform national tolerances.

THE DELANEY CLAUSE AND THE NFPA PETITION

Over the past several years EPA has publicly stated that without legislative intervention, it is bound to implement the court decree from Les v. Reilly, which interprets the Delaney Clause under a zero risk standard. Under current EPA policy, this could require EPA to revoke large numbers of food tolerances subject to the Delaney Clause and could result in a disturbance of the nation's food supply. In regards to the court mandate, EPA has stated that the Ninth Circuit decision "does not reflect good public policy or good science policy" and that the pesticides subject to Delaney "pose only a negligible risk to public health."

Yet EPA has failed to implement administrative changes which would mitigate the adverse effect of Delaney on agriculture and the nation's food supply. Despite two years of deliberation, the Agency has failed to respond to the National Food Processors Association (NFPA) administrative petition to decouple 408 tolerances from 409 tolerances. Because the Delaney Clause only applies to 409 tolerances, a decoupling of 409 and 408 tolerances would leave many safe and beneficial pesticide raw food uses and registrations undisturbed. However, under current Agency policy a 408 tolerance and its registration may be revoked if the 409 tolerance is revoked and the pesticide concentrates in processed food.

The decoupling of 408 and 409 tolerances represents the exercise of sound scientific and legal practice by EPA and could be accomplished administratively without legislative intervention.

Instead, EPA has declined to release a public statement on the NFPA petition and continues to revoke, in a piecemeal fashion, 409 tolerances. In all likelihood, the reluctance of EPA to fix Delaney from a regulatory perspective, stems from its desire to gain political pressure for passing its legislative agenda.

Although CPDA believes the Delaney Clause's "zero-risk standard is no longer scientifically justified and is virtually impossible to achieve, we do not believe the Administration's proposed health based tolerance standards, which ignore a benefits evaluation, will satisfactorily solve the Delaney problem. The FFDCa can be amended in a simple manner to reinstate the flexible concept of "negligible risk" (a concept which EPA has long supported) when setting permissible tolerances for pesticides in processed food. A strict health based standard, as proposed by the Administration, will likely cause the revocation of tolerances which do not pose a real health threat to the American public and will likely cause a disruption of the nation's food supply.

We at CPDA strongly support H.R. 1627, the Food Quality Protection Act of 1993. The bill would create a single negligible risk standard for tolerances for pesticide residues in raw commodities and processed food. EPA would be responsible for defining negligible risk in light of evolving science, taking into account different routes of exposure to a pesticide and sensitivities of population subgroups. EPA would be required, where reliable data are available, to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

BACKGROUND ON THE DELANEY CLAUSE

The U.S. Court of Appeals for the Ninth Circuit ruled in Les v Reilly on July 8, 1993 that Section 409 of the Federal Food, Drug, and Cosmetic Act, the "Delaney Clause", requires EPA to apply a "zero-risk" standard for carcinogens when setting permissible tolerances for pesticides in processed food.

The Les ruling could have a disastrous effect on the abundance and safety of our nation's food supply and the agrichemical industry as a whole. The decision could lead to the cancellation of thirty five different pesticides, which comprise more than 10 percent of the basic pesticide ingredients used in agriculture, and hundreds of different uses which were previously approved by EPA.

In 1958 Congress passed the Delaney Clause, which states in part that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." EPA had previously construed this clause using a de minimis standard for pesticide residues in processed food.

Under the de minimis standard a tolerance was granted if the human dietary risk from a pesticide was so remote that the threat of contracting cancer was "at most negligible." The Ninth Circuit, however, has interpreted the Delaney language "found to induce cancer" to mean no traces of carcinogens in residues for processed food, regardless of how borderline the response in test animals or how marginal the risk may be to consumers.

The "zero risk" standard is simply unworkable for establishing reasonable risk evaluation. When Delaney was promulgated, almost thirty five years ago, the usual scientific testing standards measured in the parts per million. Scientific detection standards now measure in the parts per trillion and greater, resulting in the detection of carcinogens which present at the most a remote and negligible threat to the public.

A mass revocation of these pesticides will likely lead to fruit, grain, and vegetable price increases and a decline in the quality of our food. A subsequent reduction in the consumption of these products by our citizens could lead to the erosion of our health and the nutritional integrity of our diets. The American Cancer Society strongly maintains that Americans need to double their present consumption of fruits, vegetables, and fiber to reduce the incidence of various types of cancers. Implementation of a "zero-risk" Delaney clause would therefore likely increase the incidence of cancer across the country.

The EPA has a vast wealth of resources, personnel, and scientific knowledge it uses to draft pesticide policy. As a federal agency it has the regulatory discretion to interpret statutes in order to effectuate this policy. EPA has long determined that a "negligible risk" standard most effectively protects the health of the American consumer and maintains the abundance of our nation's food supply.

TOLERANCE SETTING

CPDA strongly objects to the Administration's proposal for a health-based safety standard for setting tolerances which does not take into consideration benefits. A "reasonable certainty of no harm to consumers of food" standard which the Administration proposes is no different in protection than existing law, which bars residues which are "unsafe" and only allows levels which are "necessary to protect the public health." This new standard, however, does not take into account the wealth of economic and public health benefits pesticides provide consumers.

The Administration plan requires the consideration of other pesticide risks when setting tolerances. For example, drinking water or non-dietary exposures, risk of other chemicals causing the same effect and risk to potentially sensitive subpopulations would be considered. CPDA is opposed to this approach because it is purely speculative as to when and how often the combination of these elements will affect pesticide exposure in the food supply. We at CPDA believe that it is impossible to derive a true, scientific measurement of the potential risks caused by such variables. An approach which calls for the consideration of these fluctuating factors would inflate the actual level of risk associated with the presence of pesticide residues in foods.

The Administration plan also requires EPA to assume high food consumption rates at maximum residue levels to determine the safety factor for setting tolerances. The Lehman-Rowland-Bliley bill (H.R. 1627) is preferable, for it takes a more realistic view of setting tolerances. EPA would be required under H.R. 1627 to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

The Administration is very committed to maintaining and enhancing food safety for infants and children. Its proposals for tolerance setting respond directly to recommendations contained in the NAS report, "Pesticides in the Diets of Infants and Children," that EPA consider unique aspects of children's diets and non-dietary sources of pesticide exposure.

CPDA fully supports comprehensive USDA funding to collect improved food consumption data for children. We also believe that foods commonly consumed by children should be a priority in residue monitoring. It should be noted, however, that the NAS study indicated there are no identifiable problems with pesticide use in children's food, but that more in depth studies need to be taken to fully understand whether this conclusion is correct.

It is the Administration's position that where children's data is not available, EPA will employ "conservative estimates," unless the registrant can provide more accurate data. It is important that tolerances which are soundly justified by scientific evidence for the general population are not too greatly skewed by unproven subpopulation concerns.

In addition, it is important that EPA take a close and reserved look at considering non-food exposures when setting food tolerances. A reliable correlation between the two may be difficult to implement on a consistent basis.

CPDA is opposed to legislation which, in the absence of adequate data on children's food consumption patterns, allows EPA to utilize a "worst case" scenario under which assumptions of maximum dietary exposure are made. CPDA supports the more desirable alternative as set forth in H.R. 1627 which would require EPA to establish tolerances on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

TIMELY REVIEW AND ACTION ON EXISTING TOLERANCES TO ENSURE COMPLIANCE WITH THE NEW SAFETY STANDARD

A key provision in the Administration's proposal is a fundamental change in the approach to regulating the safety of pesticides in the food supply: a self-executing statutory requirement that forces all tolerances to meet the new safety standard by fixed deadlines. The Administration proposes that the review of all tolerances be completed within seven years after enactment of a legislative reform package, and that pesticide tolerances that now appear not to satisfy the safety standard be subject to special "fast track" review procedures.

The Agency presently has the means to review a pesticide tolerance if a problem with the pesticide's use is apparent. CPDA does not believe the wholesale review of every tolerance is a wise or appropriate allocation of EPA's limited resources. Only if a legitimate concern exists, should a tolerance be reviewed.

CPDA is opposed to immediate cancellation provisions for those tolerances which have not met the statutory deadline of seven years but have not shown to be a bona fide health concern. A review

provision must exist for situations in which the manufacturer has not met the burden in seven years but no real health concerns have been shown to exist.

TIME-LIMITED TRANSITIONAL TOLERANCES

Under the Administration's new tolerance review, however, EPA would have the authority to maintain tolerances for a non-renewable period of no more than five years for a chemical that does not satisfy the strict health standard if justified to maintain direct health benefits to consumers or to avoid significant disruption in the food supply. EPA should consult with the U.S. Department of Agriculture (USDA) concerning any possible disruption in the food supply.

If a tolerance can justifiably be allowed to be used for five years because its benefits clearly outweigh its risks, it should be permanently established at that level until a suitable substitute is registered. The Clinton plan provides only for a ten year period for these tolerances to remain on the market. However, CPDA believes that no time limits should apply to those tolerances which, if revoked, would create a significant disruption in the food supply. The Administration's five-year tolerance extension is underlies the fundamental rationale that all benefits must be considered when setting tolerances or registering pesticides. How can the Administration ignore benefits and believe they are worth considering in some situations and for limited time periods, but not for all tolerances and all registrations?

Inerts

The Administration's legislation to amend FFDCA, H.R. 4362, would revise the definition of a pesticide chemical to include inerts. The Lehman-Bliley-Rowland bill, H.R. 1627, includes a similar definition of pesticides. We at CPDA are strongly opposed to any efforts which would expand the definition of a pesticide to include inerts.

Under an amendment to Section 201 (a)(q)(1), the definition of a pesticide chemical is changed to also include all inert ingredients. The term "inert" should be deleted so that we can return to the original definition of a pesticide chemical. Under this definition, future residue testing could include testing for all inert ingredients, regardless of their level of toxicity.

All present residue testing for the current reregistration of particular crops and uses could be invalidated for hundreds of pesticides and thousands of uses, many of which are minor uses. Present residue testing studies for key metabolics (not inerts)

costs an average of about \$150,000 per crop use per product. By adding all inerts, the cost could jump \$50,000 to \$100,000 for each crop use for each product.

EPA has an extensive inerts program in which the Agency can require testing on any or all inerts, and has established a priority program to examine inerts of toxicological concern. In essence, EPA has the present authority to require any testing of inerts it needs. By lumping all inerts together, there is no distinction between the four categories of inerts, and no emphasis placed on inerts of toxicological concern.

By driving up the cost of residue testing on all crop uses, we further jeopardize minor uses, unnecessarily drive up the price of pesticide products to the American farmer, and place the American pesticide industry at a serious comparative disadvantage in a competitive world marketplace.

We also place a massive burden on EPA resources to require review and decision making on all inerts, thus placing the Agency in an inflexible straitjacket that unnecessarily drains money and manpower from already declining resources.

National Uniformity of Tolerances

We at CPDA strongly support Section 305(1) of H.R. 1627 because it establishes a national uniform system of tolerances. Subsection (4) clearly states that "no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residues in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination."

We cannot expect to promote interstate commerce in agricultural commodities, or the processing, storing or transporting of a food, if we allow states or local political subdivisions to impose their own tolerances for a pesticide chemical residue. Otherwise, we could find ourselves in the unacceptable position of allowing states or local governments to create barriers to interstate commerce, thus returning us to the pre-U.S. Constitution days of the Articles of Confederation period in American history. Rather than returning to the eighteenth century, we need to plan for the twenty-first century by adopting the national uniformity provisions in H.R. 1627. Unfortunately, H.R. 4362 contains no similar provision.

III. The Need For Improvements in EPA's Registration Program

We believe that EPA should channel its resources on implementing procedures which would streamline and expedite the registration process for all chemicals. Over the past several months, CPDA has worked closely with the Agency in developing a set of proposals which would help streamline the OPP registration program. Our association has submitted to EPA a detailed proposal which would makes recommendations pertaining to the coordination and streamlining of pesticide labeling, uniformity in the review of data requirements, the expansion of the Agency's notification process to allow for registrant certification of simple registration amendments, the need to fix "fast track," and the creation of single registrations for identical products in different packaging. We at CPDA believe that reform in these areas will facilitate the availability of safe, beneficial and effective products and, at the same time, will remove many of the barriers which now exist in bringing a product onto the market. CPDA would like to take this opportunity to detail several of these initiatives which we have proposed to EPA.

Single Registrations for Identical Formulations in Water Soluble Packaging

For many years the Agency has allowed different products of identical formulation to be registered under one "master label" at the Agency. Administratively, this policy made sense, for these products were the same pesticide, but were marketed in different package sizes.

Recently, however, the Agency has required product amended to be sold in different packaging or sizes to maintain its own separate registration. For example, products packaged in water soluble packaging and rodenticides packaged in closed "place pack" containers were required to maintain their own registrations, separate from the registration already established for the exact same pesticide product.

Unfortunately, this policy has dissuaded companies from marketing new products with safer packaging because of the high state and federal fees for maintaining a registration. The Agency's emphasis on safer pesticides, reduced levels of user exposure and decreased container waste, should however, make these technologies leading candidates for promotion at the Agency.

To streamline the process for registering products with the same active ingredients and same formulation, but with different packaging, so as to not require a separate registration, CPDA urged the Agency to establish procedures for registrants to notify the Agency about changes in packaging.

The main purpose of this expanded notification process is to avoid the unnecessary duplication of the registration process, to utilize the master label concept with the ability to split the label, and to allow the Agency to utilize its limited financial resources and declining manpower pool on other, more risk related issues.

The unnecessary duplication of the registration process discourages innovative ideas in packaging, delays market entry, and increases fees at the federal and state levels. By promoting new packaging, such as water soluble bags, it is possible to promote a closed system approach that enhances safety by reducing mixer loader exposure for agriculture products. It also complements the Agency's effort to reduce the number of non-recyclable pesticide containers and at the same time reduce the unnecessary use of hazardous landfills. In addition, cereal rodenticides which are sold in place packs and wax block and rodenticides which are sold pre-cut reduce exposure to consumers and users.

Existing EPA policy does not encourage or provide incentives for safer, more efficient packaging. In fact, it discourages new innovations in packaging by requiring separate registrations, delayed market entry, and increased fees at the federal and state levels.

Although EPA has consistently held a policy of promoting pesticides with reduced risk or "safer pesticides," and has recently promulgated new container regulations to reduce the number of pesticide containers and reduce exposure, it has not taken similar initiatives for water soluble packaging.

Utilizing water soluble packaging to load crop protection chemicals into spray tanks will result in a "closed" system that will significantly reduce mixer-loader exposure as opposed to the "open-pour" methods.

Across the board, it also reduces container disposal, solid waste collection, and utilization of landfills. By shifting from a liquid to a dry powder, with a water soluble bag, there is an inherent increase in safety concerning accidents, spillage, and a possible reduction in groundwater contamination. It is far easier to cleanup a breakage or spill if the product is in a dry form, compared to a liquid form.

Although rodenticide registrants are utilizing the same active ingredient, same formulation, they are attempting to develop innovative packaging concepts to meet consumer demands. The Agency has been requiring separate registrations for cereal bait formulations packaged in "bulk containers" or in small packs, commonly known as "place packs." The application directions differ for bulk bait, which requires placement in terms of ounces, whereas those for "place packs" are described by the number of packs.

In another example, one formulation of a paraffin based "all-weather" rodenticide block bait, which is scored to be broken by the user is commonly required to have a separate registration number from a product with the same formulation which is sold pre-cut into pieces. The only difference between the products is that the application directions for the first product include instructions for breaking the bait. If the Agency feels that different application directions are needed to promote consumer health and safety, registrants do not oppose putting different directions on different sizes. But many insecticides and many consumer products provide different directions for users without requiring separate registrations. In fact it is common place for Agency registered products to have one registration number for different sized packages of the same products.

Current regulations require the registrant to seek a new separate registration for each product utilizing water soluble packaging. Even if the registrant is utilizing the same active ingredient, the same formulation, with the same level of toxicity, the Agency is arguing that two package types cannot utilize the same EPA registration number if the use directions are different. It is important to note the site and dosage rates are usually the same, only the mixing instructions are different. For example, rather than require one quarter pound per acre, the registrant is requiring X number of packets per acre or X number of packets for Y number of acres. For crop protection chemical, the registrant is attempting to restate the use directions by shifting the mixing instructions, not the site or dosage rate.

By requiring a separate registration for each "new" water soluble packaging product or different rodenticide size/shape, the Agency is delaying market entry by one to two years, and forcing registrants to go through the costly and timely registration process.

The Agency is also utilizing its resources, both financial and manpower, to review and approve these additional registrations at a time of declining budgets and manpower allotments. By streamlining existing procedures, the Agency could save enormous resources, while preventing the unnecessary duplication of registrations.

Each registrant must pay additional fees at the federal and state levels for each "new" product. At the federal level, it requires \$1,300 for each product in additional maintenance fees. If also registered in 50 states, it can cost up to \$5,500 in state fees for each product.

EPA has recently notified CPDA that it intends to issue a PR Notice which will allow single registrations for identical products in water soluble packaging. CPDA is pleased that the Agency is taking this action. We believe that this action will help reduce

the disposal of containers, reduce exposure to mixer-loader employees, reduce the amount of Agency time spent on reviewing these registration applications, and save pesticide registrants as much as \$50,000 to \$100,000.

The Need to Fix "Fast Track"

For almost six years, the EPA has been implementing the provisions of the 1988 FIFRA "Lite" amendments, but has not been able to clear the backlogs that exist in the registration division. This backlog especially impacts "Fast Track" or "expedited review" products, despite Congressional authorization for up to \$2 million per year of reregistration maintenance fees to be used to implement "fast track."

On the front-end review process, the Agency has done an adequate job of reviewing the original documents and determining if they are in order and complete. This initial review has usually been completed in forty-five days. The second phase -- requiring ninety days -- provides for the finalization and approval or rejection of an "expedited review" application. It appears that "an expedited review" product gets no special handling in this second phase. It seems simply to go to the bottom of the pile.

The "ninety day" second phase has taken anywhere from six to eighteen months, with some isolated examples that required more than two years. The Agency has not moved quickly enough to solve these "fast track" problems. Some simple label changes, such as alternative brand names or the addition of alternate sources of supply to a confidential statement of formula, that take fifteen minutes to review, instead, take six months to filter through the process. Many label changes need only prompt responses, without delegation of responsibility. We see little evidence that the Agency has moved quickly enough to put the appropriate personnel in place to handle this workload.

We believe that existing resources within EPA's OPP should be utilized to address "expedited review" backlogs. Assignments of specific personnel to handle expedited review should be made. For example, one person on a product manager's team should be designated for expedited review. When he or she is caught up, then, he or she could return to other team assignments. The amount of time needed would vary from team to team, depending on the number of cases to be handled.

Under present handling of "me-too" applications or simple amendments, each of these expedited review applications is placed in one stack with all other applications. There should be two stacks -- one for expedited review, and another for other applications.

Many "me-too" applications simply take too long to review. Frequently, each application goes through a seven step review process, each of which is time consuming. Rather than a seven step process, a first level reviewer should be given the authority to complete the process.

To facilitate the quick identification of expedited review applications, the applications should be more easily recognized by color coding the application.

If the Agency fails to comply with the 90-day deadline, for whatever reason, it should provide the registrant with an up-date, and an expected timetable for completion. Without this type of status report, registrants cannot make normal business decisions or marketing plans.

The Need to Expand the Agency's Notification Process

In order to reduce the backlog in registration applications at the Agency, we at CPDA believe that the notification process should be broadened in order to expedite common product amendments which do not involve the introduction or increase in risk. We have recommended that the Agency establish a certification process by which a registrant could certify that its registration application meets the Agency's requirements and regulations for registration. The following are just a few examples of the types of registration amendments which could be accomplished through notification:

- New areas (site and pest) of use within the same category not requiring additional data;
- Use precautions related solely to a registrant's liability for efficacy, crop damage, or compatibility;
- Non-substantive label changes which do not effect the safety or manner in which the consumer understands how to use the product;
- EPA initiated label changes and environmental marketing descriptions subject to FTC restrictions; and,
- Changes in inert ingredients.

The Need to Achieve a More Effective Review of Data

We at CPDA believe that the Agency can streamline and improve data review by adopting the following suggestions:

- Notification or self-certification of acute toxicity studies, except for inhalation and dermal sensitization;

- Review and approval of data protocols in a timely manner;
- Early warning system for registrants; dialogue on issues as they arise; early consultation on PR Notices;
- Consistent review of toxicity studies; and,
- EPA's precautionary labeling reviewers need to follow the stated Agency positions in the toxicology rejection rate criteria document.

At a time of limited Agency financial resources and declining manpower, it is important that the Agency do more with less, while not impairing risk or adversely affecting man and the environment. We at CPDA believe that the recommendations set forth here in our testimony will help the Agency achieve this goal.

IV. Public Health Pesticides

In its provisions on pesticide minor uses, H.R. 4329 includes a provision, wholly supported by CPDA, which recognizes the need to protect the continued availability of public health pesticides. As such, the Administration's legislation would direct the Department of Health and Human Services and EPA to collaborate in identifying critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with HHS adopting a role similar to that filled by USDA's IR-4 Program for agricultural minor uses. H.R. 4329 authorizes appropriations of \$12,000,000 for fiscal year 1993 to be used by the Secretary of Health and Human Services in providing support for the required studies needed to continue the registration of public health pesticides.

CPDA applauds the public health pesticide provisions contained in H.R. 4329. In supporting the Administration's provisions on public health pesticides, we would also recommend that the Subcommittee incorporate into any FIFRA amendment package the provisions of H.R. 1867, introduced by Representatives Dooley and Herger during this 103rd Congress. Titled the "Public Health Pesticides Protection Act of 1993," this important legislation embodies many of the concepts set forth in the public health provisions of the Administration's bill. We believe that H.R. 1867 affords appropriate protection for many of these low volume products which are critical to preserving the public health. H.R. 1867, which has CPDA's full endorsement, is almost identical to H.R. 5110, sponsored by Congressman Herger during the 102nd Congress. The Dooley-Herger bill ensures that EPA establish guidelines that take into consideration the need for and benefits of public health pesticides used to combat disease-carrying insects and pests and to ensure that these products are not lost in the reregistration process due to economic reasons alone.

The Dooley-Herger bill contains provisions which would:

- o Define public health pesticide uses in the context of minor uses;
- o Create a separate class of pesticide registration for public health pesticides with a risk-benefit balance, which is separate from that utilized for agricultural pesticides;
- o Require that the EPA Administrator take into consideration "the differences in concept and usage" between agricultural, non-agricultural, and public health pesticides;
- o Require consultation by the EPA Administrator with the Secretary of Health and Human Services on pesticides for public health uses, similar to the existing consultation between EPA and USDA; and,
- o Expedite the registration of products necessary for the protection of public health.

On April 23, 1991, Dr. William Hazeltine, Manager-Environmentalist of the Butte County Mosquito Abatement District in California, appeared before members of the House Subcommittee on Department Operation's Research and Foreign Agriculture. More recently, he appeared before this panel during the June 8, 1993 oversight hearings on FIFRA conducted by Chairman Stenholm. During each of his Congressional appearances, Dr. Hazeltine eloquently drew attention to the need to create a public health provision in FIFRA, with an emphasis on controlling diseases transmitted by mosquitoes and other vectors.

Dr. Hazeltine's June 8th testimony states, "...It should be obvious that for good mosquito and other vector control programs to continue, professional public health decision-makers need to have a wide array of choices available to them, so that they can select the best material or method for use when control becomes necessary. If pesticides are not registered by the Federal Environmental Protection Agency (EPA) they are not going to be available for use to protect the Public's Health. While we continually look at a wide range of control alternatives, we recognize the need for effective pesticides which are registered and available for our use."

We would also like to point to the comments of Dr. John Graham which were shared with this Subcommittee on July 14, 1993. Dr. Graham is Professor of Policy and Decision Sciences at the Harvard School of Public Health and founding Director of the Harvard Center for Risk Analysis.

Dr. Graham's July 14th testimony makes a very convincing case for the human health benefits associated with the use of many pesticides. He states, "...In some situations, the loss of a pesticide may cause direct harm to public health as a result of consumer exposure to the fungi that thrive without the pesticide. For example, although many fungicides have been shown to cause cancer in animals at high doses, some of the toxins produced by fungi, such as aflatoxin, are also known to cause cancer. One of the benefits of pesticides is the human health protection resulting from destruction of fungi."

Many CPDA companies manufacture, formulate and distribute insecticides and rodenticides that attack mosquitoes, flies, ticks, mites, fleas and other insects, rats and other rodents, and that promote public health. Many of these companies, therefore, emphasize non-agricultural pesticide production and public health issues. Because we share Dr. Hazeltine's concern about public health issues, we at CPDA believe that the public health pesticide provisions of HR 1867 should be adopted as an amendment of FIFRA.

In summary, the Dooley-Herger bill recognizes the unique benefits of low volume minor use pesticide products which are widely used in public health programs to combat a host of insects and pests which transmit harmful diseases to man. It is critical that a wide variety of product choices be made available in order to maintain good mosquito and other vector control programs. Without proper public health programs, vector borne diseases such as malaria and yellow fever might once again become epidemic in the United States. We believe that the provisions contained in the Administration bill if adopted in combination with the Dooley-Herger bill will help ensure that this never happens.

V. Other Important Pesticide Legislative Issues

Additionally, we would like to comment on six other pesticide issues: 1) label reform; 2) "Me-too" certification; 3) preemption; 4) synchronization and coordination; 5) minor use; and, 6) minor use and data compensation.

Label Reform

Although EPA has taken some important initial steps to restructure and reorganize its handling of labels, we strongly support the labeling reform provisions of the soon to be introduced antimicrobial pesticide legislation, developed by the Antimicrobial Industry Coalition (AIC). Section 10 of this legislation is very similar to the language adopted by the DORFA Subcommittee on May 17, 1992, in its "en bloc" amendment. Many different EPA offices

and programs require the registrant to make changes on the label, but no one part of the Agency coordinates label changes. This amendment would require the Agency to establish a labeling program within OPP, and stipulated that one date (October 1) each year should be selected for all EPA-mandated label changes.

"Me-Too" Certification

The 1988 FIFRA "Lite" amendments mandated that the Agency establish a "fast track" or expedited review of "me-too" registrations and simple amendments (label changes), but the Agency has never fully implemented this provision. We strongly support Section 8 of legislation, developed by the Antimicrobial Industry Coalition, that creates a certification registration process for substantially similar or identical pesticides. This important reform will expedite pesticide registrations and dramatically reduces the amount of Agency resources needed to register these products.

Preemption

We at CPDA would like to express our support for legislation which would preempt local jurisdictions from enacting their own rules governing the sale and use of pesticide products. We believe that such regulatory authority over pesticides should be limited to a partnership between Federal and State governments which have the appropriate mechanisms in place to promulgate uniform, sensible regulation based on sound science.

On June 21, 1991, the Supreme Court issued its decision in the case of Wisconsin Public Intervenor v. Mortier. In its opinion written by Justice White, the Supreme Court ruled that local jurisdictions are not preempted by FIFRA from enacting their own pesticide ordinances. In essence, the Court's decision threatens to undermine the existing Federal-State partnership of pesticide regulation by opening up the field of regulation of these products to more than 80,000 units of local government.

At its May 1992 FIFRA markup of H.R. 3742, introduced by Congressman Charlie Rose during the 102nd Congress, the DORFA Subcommittee adopted an amendment which preempted local municipalities from regulating the sale or use of pesticides.

We remain committed in our support of legislation which would amend FIFRA to prohibit the local regulation of pesticides.

Coordination & Synchronization of Federal/State Data Requirements

We at CPDA strongly support legislation that would facilitate an increase in coordination and synchronization between the various states and the U.S. Environmental Protection Agency. Legislation to achieve these goals was introduced on November 22, 1991 (H.R. 3882, the "Pesticide Data Coordination and Synchronization Act of 1991") by Congressmen Steve Gunderson (R-WI) and Pat Roberts (R-KS).

In 1984, California passed S.B. 950 to require the filling of pesticide data gaps, for all products, including lawn care chemicals. To implement this law, the State adopted a definition of a "data gap," created a list of tests that need to be completed, and established a detailed timetable for filling these data gaps.

The state legislature, however, did not take into consideration the attempt of the Congress to create their own reregistration timetables when it amended FIFRA in 1988. FIFRA "Lite" was also designed to fill these same data gaps. This is a new and growing problem. Several states are now considering such legislation and Arizona has followed California's example.

The bill, according to Representative Gunderson, would have required EPA to "coordinate and synchronize" data requirements at the State and Federal levels so as to "avoid unnecessary repetition and redundancy."

Representative Gunderson stated that the legislation "calls for communication and consultation concerning requirements for generation and review of specific data between State and Federal regulatory agencies, and will foster but not require uniformity."

In his remarks, appearing in the November 22, 1991 Congressional Record, Representative Gunderson said that by "reducing the increased pricing associated with the cost of unnecessary and redundant testing," the measure would help farmers and consumers faced with the rising cost of pesticide products.

"To illustrate the need for this legislation," the Congressman stated, "it is important to note that States have been adopting laws to establish programs for filling health and safety data gaps on pesticides registered within its borders."

"In some cases," he continued, "by establishing a list of required studies, and by creating a timetable for filling these gaps, the States will disregard the efforts of EPA to establish reregistration timetables and data call-ins to fill some of these very same data gaps."

"In essence," Representative Gunderson stated, "in attempting to establish their own expedited reregistration programs to fill data gaps, the States may establish their own data requirements, and those requirements can be at odds with EPA's and cause hardship for both active ingredient manufacturers and formulators of pesticides. Additionally, standards of review of existing or newly generated data may differ."

"Unnecessary repetitive and redundant testing not only consumes valuable time and resources," the Congressman stated, "but also delays the closing of data gaps. Valuable time and resources which could be used to develop new data are wasted in refocusing on gaps that have already been or are in the process of being filled."

In his statement, Representative Gunderson also noted that many low-volume, low-profit specialty products, including antimicrobial products, may be discontinued because neither the registrant, the formulator, nor the State will pay for additional tests required on active ingredients.

"Many nonagricultural, minor use products also could disappear," he said. "Unrealistic timetables for implementing and generating these needed studies could cause some of these products to be dropped from the market."

Concluding his remarks, Representative Gunderson stated that "With adoption of this provision, pesticide manufacturers can make well-reasoned decisions as to the generation of additional data. The entire process of filling data gaps will be greatly enhanced through the exchange of information between State and Federal toxicologists and other regulatory officials."

Coordination and synchronization legislation would help reduce the cost of pesticides, including lawn care chemicals, eliminate duplicative and unnecessary testing, expedite the closing of data gaps and make sure that pesticides for farmers and consumers, especially minor use products, will be available wherever needed.

It appears that Congressman Gunderson's legislation from the 102nd Congress (H.R. 3882) will be incorporated into a comprehensive legislative package being drafted by the Antimicrobial Industry Coalition (AIC) that may be introduced as a free-standing bill or as an amendment to FIFRA. We at CPDA continue to support this legislation.

Minor Use

CPDA supports the concept of the Minor Crop Pesticides Act of 1993, H.R. 967. The retention of minor use pesticides used on low volume commodities should remain a key focus of Congress in the reauthorization of FIFRA. Minor crops grown in the United States constitute an industry with estimated sales of \$35 billion at the farmgate. These include hundreds of different crops ranging from daily foods (fruits, vegetables, and nuts) to a variety of specialty items (flowers, hops, herbs, trees, shrubs, and turf).

As you know, under the 1988 amendments to FIFRA, the U.S. Environmental Protection Agency was charged with reviewing some 600 agricultural chemical active ingredients as part of its nine-year accelerated reregistration program targeted for completion in 1997.

Since its inception, we have witnessed a dramatic reduction in the number of minor use pesticide registrations. To date, 34% of the products originally registered have been dropped. The majority of these product registrations have been held by small companies. The financial burden of maintenance and reregistration fees in combination with the enormous costs of generating the necessary data to support the continued registrations of these chemicals have contributed to their decline. Today, a number of crucial products remain at risk of disappearing from the marketplace.

EPA's accelerated reregistration program has subjected registrants to a number of data submission requirements in defending pesticide registrations for use on minor crops. The costs associated with fulfilling these requirements is formidable when one considers that for each active ingredient, there may be a number of different product formulations used on a wide variety of crops.

The members of CPDA see H.R. 967 as a step in the right direction to ensure cost-effective chemicals remain available for use on low volume commodities. H.R. 967 supplies the flexibility to EPA in addressing minor use registrations. Time extensions, waivers, use of surrogate data, and the creation of a fast track process for these registrations provides the mechanisms needed to support the continued uses of these valuable chemicals. At the same time, the bill conditions these allowances on the certainty that there will be no unreasonable adverse effects on man or the environment.

Moreover, the measure adopts a very broad definition of minor use, encompassing uses of a pesticide on animals, commercial agricultural crops and public health pesticides. A determination of minor use activity is based on economic incentives, rather than on specific acreage requirements, a threshold found in previous minor use bills. As such, current EPA policy is ratified.

Furthermore, we support the creation of minor use programs in both EPA and USDA. Programs of these sort will help in coordinating policies, consulting with growers and tracking and expediting minor use registrations.

Minor Use and Data Compensation Issues

We believe that the mechanisms found in H.R. 967, such as extensions, certain waivers and use of surrogate data, in conjunction with the present data compensation provisions found in FIFRA, provide ample incentive for pesticide registrants to support these chemicals through the reregistration process and in developing new active ingredients.

While we support the major provisions of H.R. 967, we believe the extension of time periods for exclusive use of data will not assist minor use protection, and, in fact, will actually exacerbate the problem.

The pesticide industry is similar in many ways to the pharmaceutical industry. Under FFDCA, there are limited provisions which grant patent term extension to cover, in part, some of the time lost in the FDA registration process, but it also includes provisions for generic drug registration, the elimination of data compensation provisions, and permits the testing of potential products two years prior to the expiration of the patent. These arrangements create a balanced package for both basic manufacturers and generic drug producers.

Currently, under FIFRA we find that in addition to the initial patent, the data used by a generic producer are compensated not at cost but at fully loaded value with market considerations such as early market entry. If Congress selected to extend the period of exclusivity, the result would be an unfair and inequitable solution that would only drive up the cost to farmers, ranchers, consumers and pesticide end-users. Moreover, it would destroy competition in the marketplace and would disproportionately impact small businesses that formulate or distribute many regional or local products.

We believe that these exclusive use provisions should be dropped for the following reasons:

1. It will artificially inflate the costs of nearly all pesticides and create a ten year period where the registrant can maintain a high price for all consumers and pesticide uses. This provision will affect millions of farmers, as well as countless millions of consumers who treat their lawns, shrubs, trees, and gardens.

2. This ten year exclusive use period will broadly affect most food use pesticides, including most of the List A and B food use products currently being reregistered.
3. It will create a monopoly for basic registrants that will deny formulators and distributors an opportunity to market their products for specific minor uses and prevent entry into the market.
4. It will create an economic disincentive to market existing products. For example, dealers and distributors will probably want to carry a product with the largest number of uses, and would not carry a product with 5, 10 or 15 fewer minor uses. In essence, a formulated product with fewer uses would be at a competitive disadvantage in the market place.
5. It would extend protection far beyond patent term and provide de facto patent term extension.
6. This period of exclusive use would particularly impact old chemicals being reregistered, and could effectively deny formulators and distributors entry into the local and regional markets for minor use products.
7. The provision covers all data which solely supports a minor use. It is not restricted to just residue data.
8. This provision is unneeded and unnecessary because sufficient economic incentives for data production for minor uses already exists under the EPA PR Notice 94-1 which provides for protection of data and compensation for that data. Under Section III of the Notice entitled "Data Compensation Rights of Persons Who Develop Data," EPA affirms that "data developers who develop generic or use-specific data in support of registration or reregistration of a product are entitled to the same data compensation rights as MP registrants that develop such data. They may request that they be identified on the Agency's Data Submitters List, as wanting data compensation from registrants who use their data in support of registration. The request to be added to the Data Submitters List should include the name of the active ingredient, data for which compensation is required, and their firm's name and address." Please see an attached copy of PR Notice 94-1 as an Appendix to this testimony.
9. This provision has a disproportional economic impact on small businesses that produce, formulate and distribute local and regional products for specific minor uses.

10. Most importantly, this provision reopens the controversial Congressional deliberations over data compensation, generic data registration, patent term extension, and roll-back of the Bolar v. Roche decision that occurred in the 1980's. It devises a program that one-sidedly benefits large basic producers, and creates significant economic disadvantages for small producers, formulators and distributors and denies them an ability to compete in the marketplace.

Conclusion

We at CPDA respectfully urge this Subcommittee to markup a FIFRA bill as soon as possible. We strongly support the Lehman-Bliley-Rowland bill (H.R. 1627) for its treatment of Delaney, as well as cancellation and suspension. We support H.R. 1867, the Dooley-Herger bill on public health pesticides. We also urge your support for the yet-to-be-introduced bills on preempting local jurisdictions from regulating the sale and use of pesticides, and Congressman Steve Gunderson's bill on synchronization and coordination of data between Federal and State agencies. In addition, we support Chairman E (Kika) de la Garza's minor use bill (H.R. 967), except for the provisions on ten years of exclusivity. We strongly support Sections 8 and 10 of the yet to be introduced Antimicrobial Industry Coalition (AIC) bill dealing with certification of "me-too" registrations, and labeling reform. We strongly support fixing the registration and reregistration process so that products can be handled in an efficient, effective and expedited manner. We also support portions of H.R. 4329 and H.R. 4362, the Administration's legislation to amend FIFRA and FFDCA, respectively, especially the public health provisions.

We applaud the Subcommittee for its leadership on pesticide issues and look forward to working with you during the 103rd Congress. We respectfully urge the Subcommittee to take the best of these bills and roll them all in a markup vehicle.

(Attachment follows:)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 25, 1994

Pesticide Regulation (PR) NOTICE 94-1

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, DISTRIBUTORS,
AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and
Reregistration of Pesticide Products

SUBJECT: Withdrawal of PR Notice 91-8

Effective immediately, EPA is withdrawing PR Notice 91-8, entitled "Revised Policy To Provide Applicants Other Than Basic Manufacturers An Opportunity To Submit Generic Data and Receive Data Compensation For It." That notice requested the use of a generic label statement on manufacturing use products (MPs) to effect this policy. Persons who have complied with PR Notice 91-8 may retain such statements or may delete them from product labeling, at their discretion.

I. BACKGROUND

In the mid-1980s, the Agency developed a policy for Manufacturing Use Product (MP) labeling that uses supported by the MP registrant should appear on the label and that reformulation for other uses should be prohibited. During pesticide reregistration many MP registrants have elected not to develop data in support of some label uses of their products, especially the minor uses. In accordance with Agency policy, these uses must be removed from MP product labeling.

Certain grower groups and end-use formulators have decided to fill the void themselves by submitting generic data to support the registration or reregistration of those minor uses. However, the Agency's policy for MP labeling could have the unintended consequence of denying these user groups and formulators compensation from other formulators for this data as provided under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Section 3(c)(1)(F). Because the Agency's MP labeling policy prohibits an unsupported use from appearing on an MP label, these user groups and formulators must provide the data they intend to generate to an MP registrant in order to ensure that an MP can be reformulated lawfully for the minor uses that the data support. Once the MP is supported for such uses, however, other formulators using the MP may claim the

formulator's exemption for those uses, thereby denying compensation to the user groups or formulators that developed the data. Therefore, several end-use registrants and user groups requested that the Agency establish a mechanism to ensure that the data compensation rights of grower groups and formulators generating minor use data are retained.

PR Notice 91-8 was the Agency's attempt to ensure compensation for data developed by grower groups or formulators by requesting MP registrants to include an additional generic labeling statement that permits reformulation of their products for uses other than those specifically listed on the MP label and supported by the MP registrant, provided the formulator supports such uses. This statement preserves the data compensation rights of grower groups or end-use formulators because the labeling statement would effectively prevent other formulators that did not develop data from claiming the formulator's exemption for specific uses supported by user groups or end-use formulators.

These same end-use registrants and user groups have now advised the Agency that MP registrants should not be required to adopt the generic labeling statement set forth in PR Notice 91-8. These groups have joined with the representatives of MP registrants in advising the Agency that MP registrants should be able to control the uses made of their products by controlling the MP label. They indicated that the user groups and end-use formulators must work in cooperation with the MP registrants before developing the necessary data to sustain a use which the MP registrant no longer intends to support. These groups, have, however, asked that the Agency affirm that the formulators, coalitions, manufacturers and grower groups that develop basic data are entitled to data compensation should another person rely on such data to obtain a registration.

II. Agency Action

Because representatives of grower groups and end-use formulators who requested PR Notice 91-8 believe that the Agency should not require MP registrants to adopt the label statements set forth in the Notice, the Agency sees no reason to continue the policy. Accordingly, the Agency withdraws PR Notice 91-8 and will not require MP registrants to incorporate the generic labeling statement set forth in PR Notice 91-8.

III. Data Compensation Rights of Persons who Develop Data

Although EPA is withdrawing PR Notice 91-8, it is not abandoning the principles underlying the notice. EPA affirms that data developers who develop generic or use-specific data in support of registration or reregistration of a product are entitled to the same data compensation rights as MP registrants

that develop such data. They may request that they be identified on the Agency's Data Submitters List, as wanting data compensation from registrants who use their data in support of registration. The request to be added to the Data Submitters List should include the name of the active ingredient, data for which compensation is required, and their firm's name and address. Submit such requests to Ms. Sherada Hobgood at the address under VI below.

IV. Registrant Action

MP registrants who have complied with PR Notice 91-8 may continue to use the label statement set forth in the notice¹, or may delete it at their discretion. No notification is required solely for this purpose.

Any MP registrants wishing to do so may add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of their product for a specific use or all additional uses supported by a formulator or user group. Furthermore, provided no other labeling changes are made, no notification to the Agency is required.

- (a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U. S. EPA data submission requirements regarding the support of such use(s)."
- (b) "This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U. S. EPA data submission requirements regarding the support of such uses."

Note: This notice does not alter the Agency's basic labeling policy that MP registrants include a specific list on the label of those uses for which the MP may be reformulated.

V. Effective Date

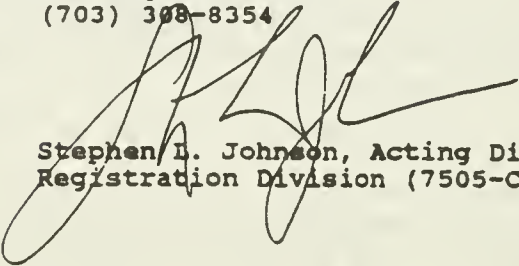
¹ "Only For Formulation Into An _____, [fill blank with Insecticide, Herbicide, or the applicable term(s) which describes the type of pesticidal use(s)] For (1) The Following Use(s): _____; (fill blank(s) with only those uses that are being supported by the MP registrant or applicant.) Conclude this statement by adding. (2) Uses For Which U. S. EPA Has Accepted The Required Data And/Or Citations of Data That The Formulator Has Submitted In Support Of Registration; and (3) Uses For Experimental Purposes That Are In Compliance with U. S. EPA Requirements."

Effective immediately PR Notice 91-8 is withdrawn.

VI. Additional Information

For further information please contact:

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Washington, DC 20460
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Stephen L. Johnson, Acting Director
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TESTIMONY OF RALPH ENGEL

PRESIDENT

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

Good morning, my name is Ralph Engel. I am President of the Chemical Specialties Manufacturers Association (CSMA) located at 1913 Eye Street, NW, Washington, DC.

CSMA has membership of some 440 firms engaged in the manufacture, formulation, distribution and sale of pesticides, antimicrobial products, automotive chemicals, detergents and cleaning compounds and polishes and floor finishes for household, institutional and industrial use. A significant number of these products have pesticidal claims and are therefore subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Specifically, CSMA represents the nonagricultural pesticide industry, including disinfectants and sanitizers, home, lawn and garden pesticides and a wide variety of pesticides for home, industrial and institutional use. Our testimony today focuses on three areas: the Clinton Proposal, antimicrobial products and other issues affecting the pesticide registration process.

I. The Clinton Proposal

Mr. Chairman, at the outset I want to note that the Clinton Administration has expended considerable effort in assembling a comprehensive FIFRA and Federal Food, Drug and Cosmetic Act (FFDCA) reform package. It has long been clear to all of us in this room that there are no political winners who will emerge from this debate. There are difficult public policy questions addressed in this package and the Administration's willingness to engage these issues is to

be recognized. Having said that, the chemical specialties industry cannot support the Clinton legislation and feels that it is not the balanced "middle of the road" proposal that its proponents would have you believe.

We wish to note that over the past few years, the Environmental Protection Agency (EPA) has expressed concern over what it considers to be the cumbersome and time-consuming process required to cancel or suspend a registration. CSMA understands the Agency's concern and believes it must be provided the tools to promptly address pesticides which pose an unreasonable adverse effect to human health or the environment. We also believe that the continued safeguards afforded through administrative adjudicatory hearings are in fact absolutely necessary and proper. This process ensures an adequate chance for rebuttal by the registrants as well as a proper forum for consideration of all relevant factors for cancellation or suspension of a pesticide.

CSMA will continue to objectively look at any reasonable proposal proffered by EPA and others concerning this issue but remains committed to maintaining appropriate procedural safeguards. Unfortunately, many of the provisions in the Clinton Package attempt to circumvent administrative protections. Accordingly, we in the chemical specialties industry have very serious concerns with the legislation. Among these concerns are:

A. Elimination of Benefits Considerations

The Administration has essentially proposed the phase-out and elimination of benefits considerations in registration, suspension, and cancellation decisions

over a period of ten years. FIFRA is the last major environmental statute which provides for a risk/benefit standard. Flexible consideration of benefits in these decisions is consistent with the FIFRA's societal risk/benefit requirements and is essential to preserving EPA's ability to take into account the value of a pesticide in determining whether or not to register the product or to let stand an existing registration.

In fact, an analysis of benefits of such products as antimicrobials which provide public health benefits is a legitimate and important consideration which must be preserved in the regulatory process. Antimicrobial pesticides (disinfectants, sterilants, industrial biocides) account for approximately 30% of all active ingredients and products registered under FIFRA. These pesticides provide substantial public health benefits by preventing or destroying bacteria, fungi, viruses and other dangerous microorganisms (legionella, salmonella, etc.). Preserving the consideration of those health benefits is absolutely critical to the public health and to this industry. Dropping this factor from the regulatory process would be a disservice to the public and would actually weaken protections for the public presently afforded under FIFRA.

The Administration's proposed elimination of benefits considerations is inconsistent with the fundamental goals of its own Executive Order 12866 on Regulatory Reform which directs federal agencies to consider the costs and benefits of available regulatory choices and to select approaches that "maximize net benefits" to society. Specifically, Executive Order 12866 signed by President Clinton on September 30, 1993 requires any agency developing a regulation to: 1) assess both the cost and benefits of the intended regulation and

propose and adopt it only if its benefits justify its costs, 2) base its decisions on the best reasonably scientific, technical, and economic information, 3) identify and assess alternative forms of regulation, 4) avoid duplicative regulations, and 5) tailor its regulations to be the least burdensome on society. We submit that elimination of benefits considerations clearly violates this Order and on this basis alone should not be included in any FIFRA legislative package.

B. Rigid Negligible Risk Standard

The narrative standard "reasonable certainty of no harm" as advocated by EPA is actually severely restricted by a statutorily prescribed numerical margin of safety (1×10^{-6}) and very conservative exposure assumptions, particularly for children and infants. CSMA would continue to support a narrative definition of "negligible risk" consistent with present risk ranges (1×10^{-5} to 1×10^{-6}) used by EPA, FDA, and other federal agencies. The risk assessment process, for cancer and non-cancer risks, should not be prescribed in statute; it should instead provide EPA with appropriate scientific flexibility and discretion.

C. Phase-Down/Phase-Out

The Administration proposal gives EPA authority to "restrict, reduce, or eliminate" the use of a pesticide where "credible scientific evidence indicates that the use of the pesticide is reasonably likely to pose a significant risk to humans or the environment." This authority would accelerate the extinction of the FIFRA cancellation process by encouraging EPA to limit or ban the use of a pesticide based upon a diminished scientific threshold.

The proposed standard itself is overly broad and would result in a reduction in the use of appropriate scientific standards to make regulatory decisions. Moreover, data upon which the decision would be based would not have undergone outside scientific peer review. The due process protections under FIFRA's cancellation process would be eliminated. Phase-out/Phase-down actions would severely damage the affected consumer products with adverse publicity, from which it would be difficult to recover even if it were later determined that the Agency was in error. Such actions would be grossly unfair and are not needed in view of current protections which mandate that regulatory actions be predicated on good science.

D. Fees

One year ago, EPA testified before this Subcommittee that it needed \$20 million through 1997 in new fees to complete its FIFRA 1988 reregistration mandates. Yesterday, the Administration outlined its revised fees proposal which now calls for more than \$60 million through 1999 in three categories (maintenance fee extension, a \$750 per product registration fee, and new active ingredient reregistration fees).

Let me simply emphasize once again that this Subcommittee and the Congress should withhold assessing any additional fees on registrants, or granting any additional fee authority to EPA pending a thorough review of the registration and reregistration programs. Such a review should include an examination of the funds collected and utilized in both programs thus far and a specific documented accounting of the use of fees collected in previous years.

EPA Assistant Administrator Goldman's recent decision to contract with an outside management consultant to give her an operational assessment of the Office of Prevention, Pesticides and Toxic Substances (OPPTS) is a courageous and valuable step in the right direction. That outside management review must contain a serious financial audit component. We look forward to working with EPA and the management consultants on this, and related issues.

E. Reduced Risk Pesticides

CSMA and the chemical specialties industry support the goal of encouraging the development and production of pesticides presenting lower risks than those presently on the market. We believe, however, that if the registration process itself were functioning properly, much of EPA's "safer pesticides policy" would not be needed.

Frankly, we fail to understand why EPA is posturing itself to take on the creation of yet another manpower intensive project to catapult, perhaps wrongfully, some applications for registrations of pesticide actives and products ahead of others (risking litigation in the process) when the competitive marketplace would accomplish this very same goal if the Agency would streamline the unnecessarily burdensome and often nonfunctioning registration program. For example, in the antimicrobial sector - with generally low risk/low exposure pesticides being used indoors - only eight active ingredients have been registered in the past ten years (6.5% of the 127 new active ingredients registered in the last 10 years).

Faced with virtually no prospect of attaining registration in a useable timeframe, companies have significantly restricted research and development activity on new antimicrobials. These delays hinder market introduction of new antimicrobial active ingredients and products posing even lower risks and perhaps providing greater efficacy than those chemicals presently in use. Similar problems with the registration process in other segments of the pesticide industry have also reduced research in new chemicals and have stymied the competitive marketplace.

Finally, the Clinton bill authorizes a cooperative agreement program under which the federal government would make grants to private groups, institutions, and individuals pursuing reduced pesticide use. The establishment, at this time, of a new federal grant program for this purpose, seems at best out of place given the internal problems with the Office of Pesticide Program's (OPP's) registration system which demand attention.

F. Label Call-In

The Administration proposes a new Label Call-In Authority which would allow EPA through a simple notice procedure to require changes in the "labeling, packaging, or composition of the pesticide." The threshold to be met by the Administrator before taking such action is minimal; the Administrator need only determine that "the risks associated with the use of a pesticide can be reduced." In case of noncompliance, suspension without hearing is authorized and recalls and compensation can be ordered by the Agency.

Since pesticide use of any kind will generally involve some level of risk, this provision would grant the Administrator broad authority to delete or restrict pesticide use which EPA has explicitly previously approved as being within an acceptable negligible risk range.

The Agency would be under no obligation to demonstrate an "imminent hazard" or even an adverse effect on man or the environment but merely that risks can be reduced. The Label Call-In procedure outlined in the bill affords the registrant scant due process protections. This provision is thus a further method to reduce due process and fairness in the regulatory process and must therefore be rejected.

G. Export Restrictions

CSMA supports a ban on the export of pesticides which have been suspended or canceled due to human health concerns. The Clinton bill appears to include non-food use pesticides in its "Circle of Poison" provision, allowing only for an exemption by the EPA Administrator on a case-by-case basis. This is inefficient and unnecessary to address the stated issue of concern -- that is dietary exposure from pesticide residue in or on imported foods. Non-food use pesticides should be specifically exempt from this provision.

H. Citizen Suits

The legislation would authorize any person to bring a federal lawsuit against EPA or a pesticide manufacturer for any alleged FIFRA violation, be it

statutory or regulatory in nature. The consequences of this new authority are likely to be expanded and frequent frivolous litigation tying up federal courts and confusing EPA enforcement priorities at large costs to producers and ultimately consumers is a certainty. The bill's whistle-blower provision would further exacerbate these concerns. With all the regulatory restrictive provisions built into the EPA Pesticide Program, this provision is unnecessary and will foster further delays in research and the marketing of pesticide products.

I. Pesticide Recordkeeping

The bill greatly expands FIFRA recordkeeping requirements by moving from "certified and individual applicators" to all "pesticide and individual users." This a potentially costly and burdensome new requirement without any corresponding recognizable environmental or public health benefit. It should be deleted.

II. Antimicrobial Registration Reform

Mr. Chairman, as you know, CSMA has for the past eighteen months worked with the Chemical Manufacturers Association (CMA), the Soap and Detergent Association (SDA), and the International Sanitary and Supply Association (ISSA) in a coalition known as the Antimicrobial Industry Coalition (AIC). We have now visited with most members and staff on this Subcommittee about the severe problems which plague EPA's pesticide registration program. We have put forward a legislative proposal which would streamline the antimicrobial registration process without compromising the

integrity of scientific review or public health. Many of the ideas contained in the AIC legislation, in fact, are reasonably consistent with the underlying principles of Assistant Administrator Goldman's own streamlining effort now underway at the Agency, and we are actively engaged in a dialogue with her staff.

The need for this legislation became apparent to us as a result of the unacceptable backlog in antimicrobial applications pending within the Agency with little or no chance to evolve within a reasonable time. The extent of paralysis became evident when it came to light that only eight new antimicrobial active ingredients have been registered by EPA within the last 10 years; while approximately 120 new non-antimicrobial active ingredients were registered for use in other types of pesticide products. This is not to indicate that this latter figure itself is reasonable but merely shows the problem facing the antimicrobial active ingredient producers.

The problem, however, also extends into end-use products where applications remain locked up within the Agency for unreasonable periods of time and the expedited review provisions of the 1988 amendments remain largely dysfunctional. With little aspect of obtaining registrations within a reasonable time period, new research and development activity on antimicrobials has been severely curtailed. The result is that the use of new antimicrobial active ingredients in formulated products which may pose reduced risks as advocated by EPA are not progressing through the pipeline to the end-use consumer. Thus, as we have repeatedly said in every hearing for the past 15 years, something must be done about the registration process within EPA. If the

Agency really wants to spur on the introduction of products posing reduced risks, than it must address this registration process. Its inability to do this over the last 15 years, despite the 1988 amendments to FIFRA, dictate that this Subcommittee move forward and address this problem now in new legislation.

Among the most serious problems within the Office of Pesticide Programs antimicrobial registration process are: (1) inadequate staffing and resources, (2) unnecessary, repetitive reviews of staff actions, (3) EPA's low priority treatment of antimicrobial applications, and (4) shifting data requirements which change without scientific justification. Our understanding is that the Registration Division's Antimicrobial Branch has had only two product managers attempting to handle 2600 product registrations and amendments each, while non-antimicrobial product managers handle approximately 1500 product decisions. In short, EPA has not assigned sufficient staff personnel to handle the volume of applications and amendments for these products in a reasonable time period.

With respect to staff priorities, EPA has focused its resources on the registration and reregistration of agricultural chemicals which the Agency has concluded presents the greatest public health and environmental risks and similarly the greatest opportunity for risk reductions. Under this system, applications and amendments for antimicrobial products experience unreasonable delays awaiting EPA staff action. Once actions are finally taken the system is plagued by consecutive reviews by several layers of EPA management. Finally, once actions have been taken, applicants often find themselves caught in the dilemma in having data requirements changed by EPA staff without scientific justification with additional studies demanded which in many cases, are

irrelevant to a product's proposed use. Registrants experience unconscionable delays as a result of EPA requests for clarification, raw data, and imposition of additional data requirements. All of these factors combine to keep these products from the marketplace because of failure to obtain registration within a reasonable timeperiod. The irony of the situation is that many of the products have cleaning and detergent capabilities which, absent the disinfectant claim, are available without any prior approval from EPA for sale to consumers.

The Antimicrobial Industry Coalition Bill seeks to address these shortcomings by significantly streamlining the registration process by establishing:

1. A statutory definition for antimicrobial pesticides which appropriately distinguishes the unique uses and benefits of antimicrobials from those of other pesticides;
2. A new division of antimicrobial pesticides to clarify, improve and consolidate regulatory requirements. This division would be provided with staff and resources adequate to permit timely and consistent decision making on the large volume of antimicrobial registration applications. These resource allocations, would more equitably reflect the fees contribution of the antimicrobial pesticide industry;
3. A registration process for antimicrobial pesticides recognizing unique uses, limited risks and societal benefits of this pesticide class without compromising scientific review of data necessary to maintain or establish public health and environmental standards;

4. A process emphasizing front-end agreement between the registrants and EPA concerning data requirements and schedules for decision making. This would provide certainty and finality and would be subject to EPA dispute resolution procedures and judicial enforcement.
5. A regulatory program whereby applicants can certify compliance with specified EPA requirements or in some cases notify EPA of compliance thus freeing EPA personnel to address registration health related reviews.

I wish to emphasize the need for inclusion of antimicrobial registration reform amendments to FIFRA in whatever mark-up vehicle is chosen. CSMA believes these problems need to be addressed in 1994, whether or not comprehensive food safety legislation is completed this year.

III. Other Areas Needing Subcommittee Attention

There are a few other areas in the regulation of pesticides which warrant Subcommittee attention. These points and suggested remedies are as follows:

A. Expedited Review

The 1988 FIFRA amendments, under Section 3(c)(3)(B) created an "expedited review" for registration applications which are identical, or substantially similar, to a currently registered pesticide product. FIFRA now requires that the applicant receive notification from the Agency as to whether or

not the application is complete within 45 days and subsequent to such determination, that these applications be approved or denied within 90 days. This process is not working and thus even simple label changes and applications to register products which are identical to other previously registered products can take over a year to complete. Congress created expedited review and specifically earmarked \$2 million to eliminate registration backlogs in 1988. Yet nearly six years later, EPA is still not utilizing this tool.

CSMA recommends that the Subcommittee legislatively compel EPA to implement a procedure whereby under FIFRA Section (3)(c)(3)(B)(ii)(I), any applicant who does not receive notification within 45 days after EPA's receipt of an application as to whether or not the application is or is not complete, then such application must be deemed by EPA as complete. Furthermore, in the event that the applicant does not receive notification as to the acceptance or denial of the application within 90 days after receipt by EPA of the complete application, then pursuant to FIFRA Section 3(c)(3)(B)(ii)(II), such application must be deemed by EPA as approved.

Under this suggested procedure, which follows the times mandated by Congress under the current law, EPA should be permitted to only refuse to issue an approved application after expiration of 90 days if the Agency, within 15 days, was planning to issue a Notice of Intent to Suspend or Cancel the active ingredient registration for the same uses. The deadlines set forth could not be extended by EPA for reasons having to do with administrative workload. Furthermore, in the event a new registrant wishes to obtain a stamped approved label for use in the states, it could do so by merely having an agent present such

label for appropriate stamping at an EPA designated office.

Under this suggested procedure, hundreds of applications for products which are similar or identical to those already registered and on the market would move quickly. Implementation of this procedure would therefore greatly assist in breaking the EPA registration log jam which is precisely what this Subcommittee and Congress directed EPA to accomplish nearly six years ago.

B. Certification and Training

In past FIFRA hearings, there has been some discussion concerning certification and training requirements and whether these should be extended to persons using general use pesticides. Some interests have advocated that commercial application of any pesticide should be made subject to certification and training standards even if the pesticide is applied incidental to employment.

Implementation of such a policy would be folly and would require certification and special training for persons such as:

- A busboy in a restaurant who wipes table tops with a disinfectant cleaner;
- A school custodian who cleans the rest rooms with a tile and bowl cleaner;
- A building superintendent who eradicates a hornets nest with general use wasp and hornet spray;
- A nurse or doctor using a hospital disinfectant;
- Or even a housekeeper who freshens up a room with a disinfectant spray.

In each of these instances, the pesticide applied is a general use product under Section 3 of FIFRA, registered as such because EPA has reviewed it and determined that it will not cause unreasonable adverse effects to man or the environment. Such factors as low toxicity, when compared to other pesticides that may be classified as restricted use, are already taken into account. EPA also approves the label and specific directions for use.

Consumers of general use pesticides can be expected to use the products safely in accordance with directions without costly and burdensome training and certification. It is not necessary or appropriate to burden the public with such requirements, which would limit an individual's ability to quickly, easily, and inexpensively solve pest problems affecting public health and safety.

We believe that certification and training requirements are appropriate for "commercial applicators" who apply pesticides as the principal part of their business and we believe any legislation concerning such certification and training should reflect this distinction.

IV. Conclusion

I want to close this morning by emphasizing to you the need for consideration of our suggested changes and inclusion of antimicrobial registration reform amendments to FIFRA in whatever mark-up vehicle the Subcommittee decides to pursue. We believe that these problems can and need to be addressed in 1994, whether or not comprehensive food safety legislation is completed this year.

I want to thank you, Mr. Chairman, and the Ranking Minority Member, and the Subcommittee staff for the focus you have brought to the shortcomings of the registration process during the past year. As always, CSMA stands ready to work with the Subcommittee and the Agency on these issues.



STATEMENT OF

EARLE K. BORMAN

SENIOR VICE PRESIDENT, INDUSTRY RELATIONS AND BUSINESS DEVELOPMENT

CHIEF ENVIRONMENTAL OFFICER

LEHN & FINK PRODUCTS

ON BEHALF OF THE

CHEMICAL MANUFACTURERS ASSOCIATION

BEFORE THE

COMMITTEE ON AGRICULTURE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

U.S. HOUSE OF REPRESENTATIVES

REGARDING

THE ADMINISTRATION'S PESTICIDE REFORM PROPOSAL

JUNE 15, 1994

Good morning. My name is Earle Borman. I am Senior Vice President and Chief Environmental Officer of L&F Products. We manufacture a number of antimicrobial products including disinfectants and industrial use biocides which are regulated under the Federal Insecticide, Fungicide and Rodenticide Act. I am speaking here today as a member of the Chemical Manufacturers Association Biocides Panel, a CMA CHEMSTAR Panel composed of such biocide manufacturers. The panel welcomes the opportunity to appear and comment on H.R. 4329.

H.R. 4329 contains a series of proposals directed at fixing some of the critical problems in the registration program. As such, it provides a good basis for productive discussion. There are a number of positive features of the bill such as the concept that registration processes can be streamlined for certain types of products, such as biologicals.

The first point of any such discussion with our industry, however, is that H.R. 4329 does not solve major existing problems in the current registration program for the antimicrobial industry and, in many cases, will exacerbate them. The primary flaw in the bill from our perspective is that it is, from beginning to end, a food-use pesticide bill.

Our products, while defined as "pesticides," are not generally applied to food or food products. They are intended to prevent or mitigate degradation, fouling, deterioration or inefficiencies caused by microorganisms in manufactured goods, chemical substances and industrial processes or systems, and on surfaces. They do not require tolerances under either Sections 408 or 409 of the Federal Food, Drug and Cosmetic Act. Thus, our products simply do not present the risks of dispersal in the environment, the concerns for integrated pest management, or

the food tolerance issues which feed the phase-down/phase-out, reduced risk and export initiatives in this bill. Our biocide products do, however, present important and significant benefits in the form of extending the useful life of machines and industrial processes, and eliminating the germs which spread disease.

The bottom line for us as an industry is that we have profound difficulty getting our products, useful and beneficial as they are, registered by EPA in any reasonable period of time. That is what needs to be fixed. We do not need more regulation of our products. We do not need, nor can we tolerate, unlimited additional fees for non-value added government reviews. We do not need more litigation. We do not need fewer opportunities for rational discussion of applicable science and appropriate risk assessment.

What we do need are:

- registration requirements that are clear, objective, and specific;
- a streamlined bureaucratic review process appropriate to the level of risk posed by our products which differentiates between major and minor actions; and
- incentives for accountability at EPA, which includes incentives to do the job that is required and to do it in a cost-effective and timely manner.

We are working within the Antimicrobial Industry Coalition, which also includes the Chemical Specialties Manufacturers Association (CSMA), the Soap and Detergent Association (SDA), and the International Sanitary Supply Association

(ISSA), to secure reforms which meet each of these goals. We all would like to see those reforms added to any bill reported out of this subcommittee.

Apart from the Panel's general comment that H.R. 4329 must be revised to ensure the appropriate regulation of antimicrobial products, the Panel has the following specific comments on some of the individual provisions of the bill.

A. The Registration Renewal Process

The Biocides Panel recognizes that this proposed new section of FIFRA is an attempt to ensure a regular means of updating the available data on pesticides which, in turn, will prevent the need in the future for the type of massive reregistration program created in the 1988 FIFRA amendments. CMA is committed to good product stewardship and concurs that this is a subject of mutual concern and interest. A critical up-front process concern must be, however, to develop a rational system that works.

As currently drafted, the interface between the registration renewal program and the reregistration process may be inconsistent. For example, at the current pace, the majority of pesticides will likely not be reregistered until 2007. H.R. 4329 would, nonetheless, create a parallel bureaucratic renewal process which would result in the registration renewal requirement being applied at about the same time, at extra cost to the registrant and possibly according to different data guidelines. In addition, any such renewal process must differentiate between products posing different risks for simple cost-effectiveness. Clearly, a return to the drawing board is necessary here.

B. Export Provisions

The Biocides Panel opposes the application of the export provisions of H.R. 4329 to its products. As previously noted, biocides are not food-use products and, thus, do not present the "Circle of Poison" issues which appear to be the genesis of the sections included in the bill. Application of the program designed to address those issues means that the biocide industry will be saddled with a significant bureaucratic and regulatory burden that will provide no commensurate protection for food supplies or foreign workers.

With respect to biocides, there is no demonstrated need nor justification for additional regulatory U.S. controls. Biocides are covered by the U.N. Environmental Programme's (UNEP) London Guidelines for the Exchange of Information on Chemicals in International Trade which provide ample regulation. The Guidelines incorporate the internationally-accepted principle of prior informed consent (PIC). The PIC principle works and is the appropriate tool for biocide export risk management.

The mechanism in H.R. 4329 for allowing export of unregistered pesticides is inappropriate for biocides. Biocides do not have tolerances. And, due to their highly specialized formulations and low volumes, many biocide formulations are unlikely to be approved for sale in three other countries with developed registration systems.

C. Cancellation Provisions

The Biocides Panel recognizes that current cancellation procedures are viewed as burdensome by EPA. It is our view that, while here as well, improve-

ments can be made, the amount of due process afforded in the cancellation process is an important and, indeed, critical right. A tremendous investment is required by both the registrant and EPA in order to secure a registration.

With reregistration, the investment by EPA and registrants has been increased. New data have been generated and evaluated by EPA. EPA has made new decisions on which products to reregister and under what conditions.

Destruction of the registrant's investment by withdrawal of a registration should require an equally close and careful review, not only by EPA, but also by an impartial decisionmaker whose judgment can be informed through cross-examination of experts with differing scientific opinions. Registrants should not be required to bear the burden of proof; it is EPA's role to demonstrate why a previously approved product has become an unreasonable risk.

But, as with many of the ideas presented in this bill, there are more moderate changes which could be very helpful. Certainly, one can envision certain situations in which modified cancellation procedures could be appropriate. For example, expedited registration for certain low-risk products could very well justify a modified cancellation provision for those products, preserving symmetry between the effort to get on the market and any effort to cancel.

D. Fees

H.R. 4329 creates multiple opportunities for EPA to assess fees to fund all of its new program activities. Thus, EPA is authorized to assess fees from all registrants for :

- the entire cost of the proposed new registration renewal program, and
- the entire cost of the proposed new export regulation program (including \$4 million annually to provide “technical assistance” to foreign countries).

In addition, EPA is authorized to collect another \$60,000 per non-food-use active ingredient for reregistration, plus \$750 per reregistered end-use product, plus “registration maintenance fees” for another two years.

The Biocides Panel cannot support any of this without a commitment that the Panel members are being asked only to fund those actions which relate to their own registration. EPA has yet to account for how reregistration fees have been spent and we request that Congress direct GAO to review how fees to date have been spent prior to consideration of any new fees.

A second important concept for us is that payment be rendered only after receipt of the service being funded — value given for value received. It is time for the EPA to begin operating on the same cost-effective and efficient principles required of industry. This requires priority-setting, budgets, and a direct correlation between the value of the service rendered and its cost to the recipient.

* * * * *

To conclude, as I began, what biocides manufacturers need are clear and objective registration standards, a streamlined registration process, and accountability. I thank the Committee for the opportunity to comment on H.R. 4329 and look forward to further constructive dialogue on these very important issues.



The Soap and Detergent Association

TESTIMONY OF GERALD R. PFLUG, Ph.D.

PRESIDENT

THE SOAP AND DETERGENT ASSOCIATION

REGARDING THE STATUS OF ANTIMICROBIAL PRODUCTS

UNDER

THE FEDERAL, INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

BEFORE

THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

OF

THE HOUSE COMMITTEE ON AGRICULTURE

JUNE 15, 1994

Mr. Chairman and members of the committee, my name is Gerald R. Pflug and I am president of The Soap and Detergent Association (SDA). The SDA is a 138 member national trade association representing the formulators of soaps, detergents and household cleaning products and those companies which supply ingredients to the detergent and cleaning products industry.

SDA's members include nationally prominent companies as well as less well known small, often family-owned regional companies. And, along with the well known formulators of highly visible consumer products, SDA members also include the formulators of industrial and institutional (I&I) products used in hospitals, nursing homes, hotels, restaurants, manufacturing facilities and public buildings.

The products of SDA members have a long history of contributing to the establishment and maintenance of the public and personal health standards to which we are accustomed. Unfortunately, these standards and their maintenance are often taken for granted in our country today. Clean clothing, bedding, cooking utensils, plates, silverware, kitchen and bathroom fixtures are, in fact, the broad base on which our exceptional standard of public health rests. The SDA is here today because of its concerns for one of the most important contributors to our country's high standards of cleanliness: antimicrobial and disinfectant cleaning products.

-2-

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), antimicrobial and disinfectant cleaning products are regulated as "pesticides" by the Environmental Protection Agency (EPA) because they are intended for preventing, destroying, or mitigating harmful micro-organisms, viruses and bacteria. Common, well-recognized examples of such products include household bleach (when such claims are made), Lysol Disinfectant Cleaner and Comet Cleanser. Less well known, though equally important, are the myriad I&I disinfectant and sanitizing products used in health care facilities, schools, business establishments, public accommodations and public buildings.

I am here today on behalf of SDA's antimicrobial/disinfectant products sector because this beneficial category of products faces a number of regulatory problems which we believe ought to be addressed through reform of FIFRA. The principal problems of concern are the following:

1. The approval process for new active ingredients needs improvement. During one recent seven year period, no new active antimicrobial agents were approved.
2. The process for registering or re-registering products is so cumbersome and attenuated that such processing may require up to two years to complete.
3. Approval of simple label changes may take nine months or more.
4. At the state level, the lack of distinction between antimicrobial products and other pesticides has had the tendency to subject antimicrobial and disinfectant products to regulations designed for agricultural pesticides.

The consequence of these regulatory dilemmas has been to impede the development and introduction of additional safe and efficacious antimicrobial products in the market place. SDA's concerns are not new. Congress attempted to address some of these and other issues from a regulatory perspective in previous FIFRA amendments.

FIFRA Section 25(a)(1), reads as follows:

Regulations.-The administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this subchapter. Such regulations shall take into account the differences in concept and usage between various classes of pesticides and

-3-

differences in environmental risk and appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.(Emphasis added).

At this point, however, we believe that more explicit amendments are indicated. If antimicrobial and disinfectant products, as a subset of nonagricultural products, were distinguished under FIFRA and provided a separate regulatory track, we believe that the approval process for these products would be facilitated.

Based on reports by our affected members, it seems that informal structures have already evolved within the EPA along the lines we are proposing. These informal arrangements have, however, proven inadequate to resolve the problems faced by the antimicrobial/disinfectant industry. Some increased degree of formalization appears to be required in order to institute a more efficient and equitable regulatory process for antimicrobial and disinfectant cleaning products.

It seems to us that the establishment of a separate antimicrobial regulatory track would benefit the EPA as well as industry by clarifying standards and establishing an effective division of labor in the FIFRA regulatory approval process. Further, it appears to us that the formalization of some of the discretionary powers currently held by the Administrator are in order to assure that antimicrobials and disinfectants receive the degree of attention they need as regulated products.

SDA realizes the enormous task currently being undertaken by EPA in the re-registration of pesticides. We also recognize that the Agency operates, as do all human enterprises, with finite resources. However, the Agency also has a responsibility to see that all its various regulated communities, communities whose ability to conduct business depend on the Agency, receive equitable allocations of regulatory resources. While priorities may need to be assigned, that assignment ought not to unduly encumber the ability of Agency-dependent, regulated industries to conduct business.

The "Federal Insecticide, Fungicide, and Rodenticide Act of 1994," H.R. 4329, deals with extremely important issues. However, the very nature of the changes proposed in H.R. 4329 makes the need to distinguish antimicrobials and disinfectant products from other FIFRA regulated products even more urgent. In fact, my primary purpose in being here today is to urge you not to lose sight of other FIFRA related matters which, while perhaps more mundane by comparison, are deserving of attention.

When I last appeared before this Committee on August 2 of last year, I said that I wished that I could offer you a solution to our concerns. I further told you SDA was

SDA Testimony
Subcommittee on Department Operations and Nutrition

June 15, 1994

-4-

working on a proposal with allied groups. As a member of the Antimicrobial Industry Coalition (AIC), SDA has participated in the development of draft legislative language addressing the definitional and regulatory issues which concern it. In the process of developing the draft language, the coalition has met with concerned parties, including the Environmental Protection Agency (EPA). At an appropriate time, we would look forward to discussing the proposal with the Committee.

In summary, the draft language would distinguish antimicrobials from other pesticides by definition as well as refine the regulatory processes for processing certain approval applications, label changes and other matters currently covered by regulation. The goal of the proposal is to amend the regulatory process in a way which will reduce unnecessary paperwork and delays for both the EPA and business both.

Mr. Chairman and members of the Committee. this concludes my formal remarks. The SDA appreciates the opportunity to be here today and I would be pleased to answer any questions you might have at this time. Thank you.

STATEMENT

OF

Warren E. Stickle, Ph.D.

Legislative Consultant

INTERNATIONAL SANITARY SUPPLY ASSOCIATION

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before the

Subcommittee on

Department Operations and Nutrition

Committee on Agriculture

United States House of Representatives

June 15, 1994

I. INTRODUCTION

My name is Warren E. Stickle and I am the legislative consultant to the International Sanitary Supply Association (ISSA). ISSA is a non-profit trade association comprised of over 4,000 member companies located across the nation. The vast majority of these companies are small businesses, 68% of which have annual gross revenues of less than \$2 million.

These companies manufacture and distribute a wide spectrum of institutional and industrial cleaning and maintenance products, including antimicrobial pesticide products such as disinfectants, sanitizers, and germicides which are regulated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Our membership distributes antimicrobial pesticides for use in hospitals, nursing homes, schools, food and beverage processing plants, hotels, restaurants, day care centers, and other institutional and industrial establishments. As such, these products play an essential role in maintaining public health and the quality of life.

Of the many benefits of antimicrobial pesticides, none is more important than the role played in the protection of public health. Microorganisms exist virtually everywhere. The uncontrolled growth of bacteria, fungi, viruses, and a host of other organisms would have a severe negative impact on public health as well as detrimental economic consequences. Fortunately, this potential impact can be minimized by the proper use of antimicrobial products.

Disinfectants, sanitizers, germicides and sterilants are antimicrobial products designed specifically to control pathogenic organisms which can be harmful, even fatal, to humans and the environment. Modern sanitation and hygienic practices are one of the reasons for the longer life expectancies and general good health and sanitary conditions we enjoy. A significant aspect of these practices includes the use and application of antimicrobial pesticides.

ISSA appreciates this opportunity to testify and we thank Chairman Stenholm and the Subcommittee for conducting this hearing. In our testimony here today, we would like to address certain elements contained in H.R. 4329 including the fee and labeling provisions. In addition, we would also like to comment on improvements to the product registration process.

II. PESTICIDE FEES

ISSA strongly opposes the creation of additional pesticide fees and the extension of existing maintenance fees as contemplated by H.R. 4329. We ask Congress not to grant EPA the authority to impose additional fees upon industry until the Agency provides a detailed accounting of the revenues it collected and expended in furtherance of the pesticide registration program. Furthermore, we oppose any fee provisions, such as those contained in H.R. 4329, that do not address the disproportionate burden placed upon small businesses.

Over the past several years, EPA has repeatedly declared that it is experiencing a shortfall of revenues necessary to complete its reregistration program. In fact, such a declaration gave rise to a compromise fee package that was adopted in 1991.

In 1991, ISSA and several other trade associations negotiated a compromise on maintenance fees with EPA that was ultimately signed into law. In essence that compromise fee package maintained the maintenance fee at \$650 for the first product, and \$1,300 for each additional product. These fees are subject to limitations. Small businesses with 50 registered products pay no more than \$38,500, while small businesses with 51 or more products pay no more than \$66,500. This fee structure generated \$15.1 million, \$1.1 million more than the statutory goal of \$14 million.

Once again, appearing before a joint House-Senate Congressional committee hearing on September 23, 1993, EPA estimated that the current reregistration shortfall was \$20 million. The fee provisions of H.R. 4329 are intended to address this shortfall by extending EPA's authority to levy maintenance fees for two years. In addition, H.R. 4329 would impose a \$120,000 supplemental reregistration fee on an active ingredient registered for a major food or feed use, and a \$60,000 supplemental reregistration fee for active ingredients registered for non-agricultural uses. Furthermore, H.R. 4329 would establish a \$750 per product fee which could be adjusted by EPA to ensure that at least \$4 million would be generated over the four year period following enactment.

Based on these fee proposals, we estimate that total revenues of over \$60 million will be generated, substantially more than the \$20 million shortfall declared by the Agency. We base our estimate on the following. First, it is proposed that the maintenance fee provisions be extended for two years. Presently, maintenance fees generate \$15.1 million per year. Extending EPA's authority to levy this fee for two years would raise an additional \$30.2 million.

Secondly, the proposed supplemental reregistration fees of \$120,000 and \$60,000 are set at approximately 80% of the original reregistration fees enacted in 1988. When one considers that in 1989 EPA collected \$35 million in reregistration fees, we can expect to collect approximately \$28 million, or roughly 80% of the 1989 levels. Lastly, the proposed product registration fee of \$750 is designed to generate \$4 million.

Based on these calculations, the proposed fee provisions of H.R. 4329 would generate \$62.2 million, over \$40 million more than EPA's estimated shortfall. This glaring inconsistency, alone, demonstrates the need for a complete explanation of expenditures for the registration and reregistration programs including expenditures for expedited registrations (i.e. "fast track" registrations). ISSA urges Congress to require EPA to provide a clear and detailed accounting of how monies have been spent since the reregistration program was created under the 1988 amendments to FIFRA. Once we have a clear understanding of the costs and expenditures associated with the reregistration program, we can determine if there is a need to generate additional revenues. To enact fees as contemplated by H.R. 4329 without the benefit of such an assessment would be premature.

EPA's declared need for additional revenues must also be viewed in the context of EPA's present efforts to "reinvent" the Agency. Like all other federal agencies, EPA is attempting to streamline its operations to create a more effective and efficient Agency. In essence, EPA is restructuring itself so that it can do more with less resources. We commend EPA for these efforts, and in fact have been working with the Agency to help develop specific proposals.

EPA has responded positively to many of industry's suggestions and is proceeding at an aggressive pace to implement various recommendations. In fact we expect EPA to implement a number of changes within the next 4 to 6 months. For example, the Agency is proceeding with procedures that would allow simple amendments to product registrations to be handled by notification. The Agency is also working to implement process improvements in regard to acute toxicity reviews and the labeling review process.

It is our belief that these and other proposed changes will streamline the operations of the Office of Pesticide Programs (OPP) by improving certain efficiencies and eliminating unnecessary waste of limited Agency resources. It is likely that many of these changes will result in savings to the Agency. Consequently, ISSA believes that it would be best to first evaluate the results of the administrative improvements EPA is attempting to implement before we assess EPA's declared need for additional resources.

More specifically, ISSA strongly believes that it is premature to address the continuation of maintenance fees at this time. An extension of EPA's authority to levy maintenance fees until 1999 does not have to be considered until we move closer to that date. In fact, there will be additional opportunities to review this issue prior to 1998 during additional FIFRA reauthorizations. At that time Congress will have the benefit to see what impact the various streamlining reforms have had on OPP resources, and will be in a better position to judge the need for additional resources.

Moreover, it is important to note that EPA is seeking an extension of maintenance fees until 1999, but it is not seeking an extension of the prohibition of registration fees during the same time period. Therefore, under H.R. 4329, registrants would have to pay both maintenance fees and the new product registration fees.

The consequences of such a fee system are especially burdensome to small businesses who produce low volume antimicrobial pesticides. In effect, under H.R. 4329, these companies will have to pay an annual fee of \$2050 to maintain their product registration (i.e. a \$1300 maintenance fee and the proposed \$750 registration fee). To understand the true impact of this proposal we need to place it in the context of state registration fees. It now costs well over \$5,000 to register one pesticide product in each state. Therefore, the total cost to a firm who wishes to market its product nationally would be \$7,050.

As mentioned previously, ISSA is comprised primarily of small businesses, the majority of which generate less than \$2 million per year in the sales of cleaning and maintenance products. Furthermore, antimicrobial pesticides are produced in low volumes. The specialty market in antimicrobial products has been successful because small formulators have been able to produce minimum quantities of antimicrobial products for limited uses. Many of these products generate annual sales that are measured in the tens of thousands of dollars. These products must pay the same fee as agricultural pesticides that generate sales in the millions of dollars.

Therefore, the pesticide fee provisions of H.R. 4329 would have an unreasonably disproportionate adverse economic impact on small formulators of antimicrobial products because the fees paid by these companies represent a substantially higher percentage of their total sales

compared to larger companies. Such a fee system upsets the competitive balance between large and small firms. Therefore, ISSA opposes any fee system that does not take into consideration small business concerns.

III. LABEL CALL-IN AUTHORITY

ISSA supports the Administration's proposed language that would establish a uniform compliance date for label changes intended to reduce potential risk associated with the use of a pesticide. However, we strongly object to the creation of new suspension and recall authorities which would allow the Agency to take drastic action against pesticide products sold or distributed in violation of the label call-in provisions of H.R. 4329.

Over the past few years, ISSA has advocated the adoption of a uniform compliance date for label changes required by EPA to reduce the burden of multiple label changes that may be required over the course of a year. To this end we support the Administration's proposal which would set one annual date by which registrants must comply with EPA mandated label changes intended to reduce potential risk associated with the use of a pesticide product.

While we applaud the Administration for moving forward with this proposal, we believe it should be expanded upon by establishing an office within EPA that would be responsible for coordinating all EPA required label changes. ISSA believes such an office is necessary because there are numerous offices and programs within EPA that require modification to existing pesticide product labels, but there is no internal coordination of these various label changes.

EPA requires, at various times, numerous amendments to existing labels. The changes might reflect a new active ingredient, an inert or a different use. Other changes are made to incorporate a new set of directions or warnings about use or specific health and safety instructions. At other times, EPA may require the label to be modified to include new instructions for proper disposal of the container. In addition, specific programs within EPA, such as the Label Improvement Program, also require changes to labeling content.

In essence, many different offices and programs within the Agency require registrants to alter their labels. However, there is no mechanism in place through which the Agency is able to coordinate these various label changes. As a consequence, companies may modify their label to address one program's requirements, only to find several months later that they must, once again, alter their label to comply with another EPA requirement.

This lack of coordination is especially burdensome to ISSA members who formulate and distribute private label products. It is not uncommon for formulators to sell one product under as many as 20 to 30 different private labels. Furthermore, companies may have as many as 100 product registrations. As a result, one label change required by EPA results in the printing of thousands of new labels, only to find that another program or department requires additional changes just a short time later. This lack of coordination often results in a company discarding thousands of dollars in labels because they are made obsolete by another EPA directive.

Moreover, there is a distinct lack of coordination between product managers, Label Improvement Program personnel and other EPA staff in formulating label requirements. This internal lack of coordination often leads to conflicting instructions from various Agency personnel as to specific labeling language for virtually identical products. The result can be confusing and frustrating for industry in its attempts to comply with its labeling responsibilities.

ISSA, therefore, recommends that H.R. 4329 be revised to establish one office within the Agency that would be responsible for coordinating all label changes required by the various programs and divisions within EPA so that there is no confusion about the necessary elements needed to comply with the various EPA required label changes.

Despite the positive move in establishing one uniform compliance date for label changes, ISSA takes exception with those provisions of H.R. 4329 that would authorize EPA to suspend and recall pesticide products that are sold or distributed in violation of the requirements issued pursuant to the label call-in provisions of H.R. 4329.

Under current law, only those pesticides that are suspended or cancelled for health and safety concerns can be made subject to a mandatory EPA recall. H.R. 4329, as drafted, however, would expand the scope of products which could be subject to a mandatory recall to virtually any pesticide with any labeling violation, no matter how minor. As a matter of policy, we should not subject a minor labeling violation to the same penalties as those that apply to products suspended and cancelled because of health and safety concerns. ISSA, therefore, encourages members of the Subcommittee to reject those provisions that would allow for the recall of pesticide products for even the most minor oversights in complying with labeling directives.

For essentially the same reasons, ISSA also opposes those provisions of H.R. 4329 that would allow EPA to issue a suspension notice for even relatively minor inadvertent label violations. Under present law, EPA may issue a suspension notice only if the Agency determines that a product poses an "imminent hazard." H.R. 4329, however, would expand the Agency's authority to suspend products that had even the most minor of labeling violations regardless as to whether it had an adverse impact on health and safety. ISSA opposes any attempt to expand its suspension power to cover such minor labeling violations.

III. IMPROVEMENTS TO EPA REGISTRATION PROCESS

EPA pesticide product registrations are not being processed in the most effective and efficient manner. These circumstances have created a backlog of registrations which has had a disproportionate impact upon antimicrobial products. ISSA, in conjunction with other industry groups, has been working with EPA in developing administrative policies which would streamline the OPP registration program. Specifically, ISSA has proposed that EPA adopt strategies that would allow the Agency to meet the requirements of the "fast track" registration program. In addition, we believe the notification process should be broadened to encompass relatively minor registration activities.

Antimicrobial products have been unreasonably adversely affected by the backlog in the EPA registration process. Disinfectants, germicides, sanitizers and other antimicrobial products provide substantial public health benefits by preventing or destroying bacteria, fungi, viruses, and other dangerous microorganisms such as legionella and salmonella. These products play an essential role in the maintenance of sanitary and healthful conditions in hospitals, nursing homes, schools, day care centers, food and beverage processing plants, restaurants, hotels, and many other institutional and industrial establishments and even private homes. In a very substantial way, these products contribute to the overall quality of life that we enjoy today.

Despite these significant benefits, EPA assigns antimicrobial products a low priority in the registration process because of the low risk associated with these products. Unlike other pesticide products, antimicrobials are considered low risk for many reasons:

1. Applications of antimicrobials are generally indoors and in very small quantities, resulting in minimal exposure to the environment and man.
2. Dietary exposure is not a concern with this category of products.
3. In general, antimicrobials are formulated in a manner to provide for their safe use by minimizing the amount of active ingredient present in the product.
4. Industrial biocides are generally used in closed or controlled systems (i.e. water cooling systems, or product preservation uses) which virtually eliminate risks to human health and the environment.

As a pesticide class, antimicrobials provide substantial societal benefits while presenting minimal hazards to man or the environment. Ironically, EPA's policies have frustrated the introduction of significant new antimicrobial products. In fact, during the past eight years only one new antimicrobial active ingredient has been registered by EPA. By comparison, during that same time period approximately 100 new non- antimicrobial active ingredients were registered.

Antimicrobial pesticides account for approximately 35% of all active ingredients and pesticide products currently registered under FIFRA, and generate about \$4 million in annual maintenance fees out of a total of \$15 million in fees collected annually. At the present, the EPA Registration Division's Antimicrobial Branch has only two product managers attempting to handle 35% of registered active ingredients. The other two registration review branches handling the remaining 65% of registered actives and products are manned by nine product managers. Consequently, each of the two antimicrobial product managers is responsible for about 3,500 registrations, while each of the product managers handling other pesticides are responsible for less than 1,400 registrations.

This disproportionate skewing of resources has virtually paralyzed the registration of antimicrobial products. Not only has EPA's policy thwarted the timely introduction of new products and active ingredients, but it has frustrated the timely filing of minor amendments to existing registrations. A recent survey of ISSA members reveals that registrations for minor

amendments that could literally take 15 minutes to process are taking anywhere from 6 months to up to 1 1/2 years. The primary reasons for these delays as cited by survey respondents include:

1. Inadequate number of personnel.
2. EPA's claim of lost mail or paperwork requiring the need for resubmission.
3. Inconsistent requirements for labeling language and data.

One respondent pointed out that it has repeatedly taken approximately one year for it to receive approval for its "me-too" antimicrobial registrations. However, the same company has been able to receive approval for a non-antimicrobial product "me-too" registration in just over 3 weeks.

These delays are not only inequitable but are also unacceptable. The EPA registration process must be improved and not continue to operate as a barrier to market entry thereby denying the public access to better products. ISSA suggests that Congress direct the Agency to make improvements to the "fast track" registration program as well as expand the scope of registrations that could be handled by a notification process.

A. Fast Track Registration

For the past 6 years, EPA has been attempting to implement the provisions of the 1988 amendments to FIFRA which require the Agency to expedite "me-too" registrations and other minor amendments. To date, EPA has been unsuccessful in executing this Congressional mandate. Fast track registration requires EPA to expedite the processing of product registrations that are identical or substantially similar to existing pesticide products and for which no scientific review of data is required.

Under this expedited process, EPA must inform the registrant within 45 days as to the completeness of the application. EPA then has 90 days to approve or deny the application for registration. Although EPA has complied with the 45 day limitation, it is rare that the 90 day deadline is met by EPA. As described previously, ISSA members have pointed out numerous instances where it has taken 6 months to 18 months to process their fast track registration. This delay creates an anticompetitive situation, especially for a small company whose only advantage is the speed with which they can bring a product to market. More importantly, this situation denies the public the benefit of new and improved products.

In order to address these shortcomings, ISSA suggests that existing resources within OPP should be used to address the backlog of fast track registrations. Assignments of specific personnel to handle fast track registrations should be made. For instance, one person on a product manager's team should be designated to process expedited review registrations. When that person has relieved the backlog, he or she can be returned to other team assignments. In addition, ISSA encourages EPA to devote staff and resources adequate to permit timely and consistent decision making on the relatively large volume of antimicrobial registrations. Resource allocations should more equitably reflect the amount of fees generated by antimicrobial

products.

Furthermore, under present processing of me-too applications and simple amendments not requiring scientific review, each of these fast track registrations is placed in one stack with all other applications. ISSA believes that EPA should institute a two stack approach: one for fast track registrations and another for other applications. This process would help ensure that fast track registrations are not lost in the crowd and are given the proper attention.

Under present policy, EPA uses a seven step review process for all registrations including fast track. Such a process is unnecessary for most fast track registrations because a decision can often be made early on in the process. Consequently, the seven step process unreasonably adds to the length of time necessary to process a fast track registration. ISSA encourages EPA to provide a first level reviewer with the authority to complete the process at the first step thus avoiding undue delay.

ISSA also believes that the color coding of fast track registrations would help ensure their expeditious processing of fast track registrations so that they can be more easily recognized. In the alternative, a pressure sensitive "tab" can be attached to the application. Either one of these alternatives would allow for the fast track registration to be more readily distinguishable. At the present, a fast track registration application is virtually indistinguishable from other registrations increasing the likelihood of it not being processed in a timely fashion.

Lastly, we believe FIFRA should be amended such that if the Agency fails comply with the 90 day fast track deadline that such application should be deemed granted. At the very least, EPA should be required to provide the registrant with an update and an expected timetable for completion. Such information is essential for registrants to make calculated business decisions. At the present, no such communications exist.

B. Expansion of Notification Process

In order to reduce the present backlog and to free up Agency resources for other more important tasks, ISSA strongly believes that the notification process should be broadened in order to expedite common product amendments which do not involve the introduction or increase in risk. ISSA has recommended to EPA that the Agency establish a certification process by which a registrant could certify that its registration application meets the EPA's requirements for registration. The following are some examples of the types of registration activities that should be accomplished through the notification process:

1. New areas (i.e. site) or use within the same category not requiring additional data (i.e. hard surface kitchen; hard surface bathroom).
2. EPA initiated label changes (e.g. new container disposal regulations).
3. Environmental marketing descriptions subject to FTC restrictions.
4. Notification or self-certification of acute toxicology studies, except for inhalation and dermal sensitization.

ISSA strongly believes that the expansion of the notification process is essential to reduce the existing backlog so that the Agency is able to free up valuable but limited resources. Just as important, the expansion of the notification process should also help ensure that any future registration backlogs are avoided.

IV. COORDINATION AND SYNCHRONIZATION OF PESTICIDE DATA REQUIREMENTS BETWEEN EPA AND THE STATES

ISSA encourages the Subcommittee to approve legislative language which would facilitate the coordination and synchronization of data between the states and the U.S. Environmental Protection Agency. Such coordination and synchronization is essential to avoid redundant testing and unnecessary and substantial expenses.

The present problem is exemplified by California's Birth Defects Prevention Act, S.B. 950. This legislation requires the filling of data gaps for all pesticides including antimicrobial products. in order to implement S.B. 950, California adopted a definition of a "data gap", established a list of tests needed to be completed, and set a time table for filling these gaps. in so doing, the State has disregarded the efforts of Congress in establishing its own expedited reregistration program in the 1988 amendments to FIFRA which were designed to fill essentially the same data gaps.

In effect, California has established an agenda and time table that duplicates and conflicts with federal requirements. Such inconsistent requirements result in unnecessary, repetitive and redundant testing that not only consumes valuable time and resources but also delays the closing of data gaps. Valuable time and resources that could be used to develop new data are wasted in refocusing on gaps that have already been or are in the process of being filled.

The additional and conflicting data requirements artificially raise the cost of manufacturing and distributing pesticide products. It is important to note that many low volume, low profit specialty antimicrobial pesticides may be discontinued because neither the registrant, the formulator, nor the State will pay for the additional tests required on active ingredients. In fact these additional costs have resulted in the cancellation of numerous antimicrobial product registrations in California. This pattern is likely to continue as other states enter the picture once again forcing other necessary and useful products off the market.

Therefore, ISSA strongly encourages Congress to explore legislation that would facilitate the coordination and synchronization of data requirements between the states and the EPA. such legislative action will help stabilize the cost of pesticide products by precluding unnecessary and redundant testing, thereby ensuring the continued availability of a wide range of antimicrobial products.

IV. PUBLIC HEALTH PESTICIDES

H.R. 4329 contains a provision, supported by ISSA, which recognizes the need to protect the continued availability of public health pesticides. Specifically, the Administration's legislation would direct the Department of Health and Human Services and EPA to collaborate in identifying critical public health minor uses that might otherwise be lost and to arrange for necessary data support. In this regard, H.R. 4329 authorizes appropriations in the amount of \$12 million to be used in providing support for the required studies needed to continue the registration of public health pesticides.

ISSA supports the public health pesticide provisions contained in H.R. 4329. In supporting these provisions, we suggest that the Subcommittee incorporate into FIFRA amendments the provisions of H.R. 1867 introduced by Representatives Dooley and Herger, and more formally known as the Public Health Pesticides Protection Act. This legislation ensures that EPA establish guidelines that take into consideration the benefits of public health pesticides, and to ensure that these products are not lost in the reregistration process due to economic reasons alone.

H.R. 1867 was introduced to provide recognition and relief for pesticides registered for public health purposes. The legislation would extend special consideration and protection to pesticide products used to maintain good mosquito and other vector programs. In addition, H.R. 1867 would extend the same treatment to certain disinfectants, sanitizers, and other antimicrobial products.

ISSA supports H.R. 1867 because it recognizes the importance of these products in maintaining safe and healthful conditions in society. These products, however, have experienced tremendous regulatory burdens because they are treated just like agricultural pesticides in many cases. These burdens have become so substantial that many products have been dropped from the market because it is no longer economically feasible to maintain their EPA registration. Consequently, many products essential to the maintenance of safe and healthful conditions will continue to be lost unless some relief is provided.

ISSA believes that H.R. 1867 provides that relief. Specifically, H.R. 1867 would accomplish the following:

1. The bill would define "public health pesticides" in the context of minor use to include a pesticide which is used in the prevention or mitigation of viruses, bacteria, or other microorganisms that pose a threat to public health.
2. Create a separate class of pesticide registration for public health pesticides with a risk benefit analysis, separate and distinct from that utilized for agricultural pesticides.
3. Expedite the registration of pesticides necessary for public health protection.
4. Require EPA to take into consideration the differences in concept and usage between agricultural, non-agricultural, and public health pesticides.
5. Require EPA to consult with the Secretary of Health and Human Services on pesticides for public health uses.

For these reasons, ISSA seeks the inclusion of H.R. 1867 into any set of FIFRA amendments the Subcommittee ultimately approves.

V. CONCLUSION

ISSA commends the Subcommittee for conducting these hearing and encourages it to move forward and mark up a FIFRA bill as soon as possible. ISSA objects to any FIFRA package that would create new pesticide fees or extend existing maintenance fees. Such action is premature and should only be considered after we have received an accounting from the Agency.

ISSA supports the provision in H.R. 4329 that establishes one uniform compliance date for label changes. However, we encourage the Subcommittee to incorporate language that would establish a central office within the Agency to coordinate all such label changes. We firmly believe such an office is essential not only to address timing problems, but also to address inconsistent labeling language requirements. While we support the uniform labeling compliance date, we oppose those provisions of H.R. 4329 that would expand the EPA's authority to suspend and recall products whose label may deviate even slightly from the Label Call-In provisions of the bill.

ISSA also encourages the Subcommittee to incorporate provisions that would facilitate the coordination and synchronization of data requirements between the state and federal governments. Lastly, ISSA urges the Subcommittee to expand on the public health pesticide provisions of the Administration's bill by incorporating the language of H.r.1867.

We thank the members of the Subcommittee for this opportunity to express our views on this subject of utmost concern to our industry.



Responsible Industry for a Sound Environment

Testimony of Allen James, Executive Director

Before the

Subcommittee on Department Operations and Nutrition
Committee on Agriculture

United States House of Representatives

June 15, 1994

RISE -- Responsible Industry for a Sound Environment -- is a not-for-profit trade association which represents the basic manufacturers, formulators and distributors of turf, ornamental, pest management and vegetation control pesticide products. RISE supports appropriate environmental legislation, when based upon demonstrated need and sound science. For that reason, we appreciate the opportunity to comment on the various food safety and FIFRA reform proposals contained in H.R. 4362 (the "Pesticide Reform Act of 1994"), and H.R. 4329 (the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1994").

Support for "Delaney Reform"

Although RISE is primarily interested in "specialty" pesticide (non-agricultural) issues, reform of the Delaney clause

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is an important issue for our members. If the Delaney clause is not repealed, or if EPA's policies implementing it are not revised, access to valuable pesticide products may be at risk. Under EPA's current coordination policy, product registrations, as well as their tolerances, are susceptible to cancellation and revocation. Many of the active ingredients which are registered for agricultural uses are also registered for specialty uses as well. In our experience, if the larger agricultural use is lost, in most cases there will not be enough resources generated from sales under the specialty uses to justify the cost to continue the "specialty" registration.

The Delaney reform RISE envisions could take one of two forms: (1) Congress could excise that clause from §409 of the Federal Food Drug and Cosmetic Act (FFDCA), thus reconciling the conflict in current law as suggested by the National Academy of Sciences in its Delaney Paradox report, or (2) EPA could revise its outdated policies which were designed in an attempt to implement the Delaney clause. As to the latter, for nearly two years EPA has had before it a petition urging, among other things, reconsideration of its concentration and coordination policies, and the definition of processed food.

In addition, last summer in objections related to Les v. Reilly, EPA was asked to review the methods it uses to determine whether a compound "induces cancer" in man or animals, the way it determines whether a test is "appropriate," and whether the results of those tests are relevant to humans, all within the

meaning of the Delaney clause. Although the changes sought are legally permissible (in fact, we believe they are obligatory), to date EPA has not responded any of these requests. With the policy changes suggested, the number of agricultural and specialty pesticide products affected by the Delaney clause decrease, thus greatly reduce the need for immediate legislative reform.

Comments on H.R. 4362

We generally commend the Administration for its efforts to create a single negligible risk standard, thereby reconciling FFDCA with FIFRA as recommended by the National Academy of Sciences ("NAS") and virtually every party involved in this debate. We also appreciate that the bill attempts to move away from Delaney's unrealistic "zero-risk" standard. However, we are concerned that the exaggerated assumptions, detailed risk assessment requirements, and other inflexible provisions will in fact create another Delaney-type scenario.

Also disturbing to RISE members is H.R. 4362's elimination of virtually all consideration of the benefits which pesticides provide. Decision making based on risk alone is scientifically unjustified, and will result in uninformed agency action. We believe the Administration should carefully reconsider their position on this issue.

At several places H.R. 4362 also requires EPA to consider the effects from non-dietary exposure to pesticides. In making

tolerance and other decisions, EPA is directed to "fully" consider such exposures. Although the NAS report on pesticides in the diets of infants and children recommends that EPA "consider" all routes of childhood exposure to a pesticide, it did not recommend that EPA "fully account" for the exposure. This distinction is small, but significant for two reasons.

First: reliable data on non-dietary exposure (particularly exposure exclusive to children) simply does not yet exist. We believe that the level of non-dietary exposure to all people is actually extremely low. Initial data from several recent studies support that conclusion, including studies performed by the University of Cincinnati, and by the University of Guelph in Canada. For our part, RISE is supporting the development of an industry task force to collect data specifically on residential and lawn exposures so that we will be better prepared to address this issue.

RISE also supports work being done by the Exposure Assessment Specialty Group of the Society for Risk Analysis to provide education to exposure assessors about how residential-type exposure assessments can be performed. This independent professional group is also developing a state-of-the-art resource book for collecting and reviewing the data collected.

Second: because reliable data does not exist, it is simply not yet possible for EPA to "fully" account for such exposure. Any attempt to do so would be wishful thinking, at best. We fear that the "fully account" requirement will prevent EPA from making

timely decisions on registration and tolerance petitions, further delaying an already cumbersome process. Until such time as reliable data become available, and until EPA has established the procedures and protocols to "fully account" for non-dietary exposure, we urge Congress to refrain from mandating such restrictive legislation, and we urge EPA to use only existing, reliable data.

Comments on H.R. 4329

Generally speaking, RISE supports amendments to FIFRA designed to make regulation more efficient and responsive. We believe that there is general agreement that areas such as cancellation, reregistration, and minor use, among others, could benefit from revision. Unfortunately, the bill offered by the Administration amounts to a wholesale overhaul of virtually every section of FIFRA, throwing in a significant measure of new and untested authorities. We believe that reform of this magnitude is unnecessary, will divert precious EPA resources from registration and reregistration, and cost taxpayers and registrants dearly for very little in actual improvement.

Phase-Out/Phase-Down

The proposal for "phase-down/phase-out" is a case in point. This new authority is riddled with vague and uncertain terms ("credible" scientific evidence, "reasonably likely to pose," and "significant risk"), while simultaneously giving EPA extraordinary authority to all but eliminate the use of a

pesticide by notice!

In addition to having tremendous potential to disrupt both the manufacturing and use of all classes of pesticide products, this authority is not needed. The existing risk standard, and cancellation and suspension authorities, are surely sufficient to address any real risk EPA may encounter. If they are not, the shortcoming should be identified and the provision amended.

Cancellation

The cancellation provisions of H.R. 4329 are also disturbing. EPA proposes to do away with the existing due process rights found in current law with an informal rule making which will provide none of those important protections. Further, EPA proposes to shift the burden of proof from the party challenging the registration to the registrant. Finally, the standard for review of agency action has been lowered so that virtually any administrative decision would be upheld on appeal. There is absolutely no justification for taking away these extremely important due process rights. If EPA is concerned that cancellation takes too long, then deadlines should be imposed. If there are other concerns, they too should be addressed. However, as they are presently written, the proposed cancellation amendments are unacceptable.

Label Call-In

While the Administration's proposal on "label call-in" has conceptual merit, their legislative language presents significant concerns to the specialty and retail segments of the pesticide

industry. RISE agrees that an annual date for label changes which are truly small would be beneficial. This bill, however, would allow EPA to effect an extraordinarily broad range of changes in product labeling, packaging or even composition if the Administrator determines "that the risks associated with the use of the pesticide can be reduced." The goal of reducing risk is one which RISE endorses. Our members spend millions of dollars per year on research designed to bring only the best in new products and technologies to market. Our packaging is the result of careful research and years of experience, and is designed for safety and utility. The content and warnings required on our labels are already the product of extensive EPA regulation, review and approval. As written, this proposal threatens to undermine that process.

Registration Renewal

Implicit in this proposal, also known as the "sunset" provision, is the idea that all pesticides on the market should be subjected to some kind of ongoing review process. We have no objection to that goal. However, members of RISE have spent over a million of dollars under the current reregistration program alone. Because we believe in its goal, we will continue to honor our commitment to that process. Although plagued with delays, reregistration is essential, and its success is critical to public confidence in both EPA and our products.

While we are mindful of the need to establish an ongoing review program, we fear that embarking on a new registration

renewal program without first completing reregistration would be a serious mistake. By grossly underestimating both the cost and effort needed to complete reregistration, that process has suffered from a lack of credibility. All of us -- EPA and registrants -- have learned important lessons which would be critical to the success of any ongoing review program. Those lessons should be acknowledged and incorporated into any new program, but this bill makes no attempt to do that. While RISE opposes this particular provision, we would like to establish a dialogue with EPA and others on how such a program could be effectively and efficiently operated after the reregistration program is substantially complete.

Fees

RISE is not unsympathetic to the resource demands which have been placed upon EPA. Like most businesses, EPA is being asked to do more and more with less and less. We are very concerned, however, that EPA has elected to propose new authorities and programs, often without clearly demonstrating a need, rather than refining existing authorities. Of course, EPA has also proposed imposing user fees to pay for those authorities. No less than 5 new fees would be imposed under EPA's proposal. Yet no apparent effort has been made to estimate how much any one of those programs or fees would cost industry. RISE respectfully requests that EPA be required to (1) provide estimates of how much needs to be raised under each new and existing fee provision, (2) demonstrate that the authority and fee is truly necessary and

that the need cannot be met less expensively, and (3) that an annual accounting be made which documents how monies collected were in fact spent.

Citizen Suits

We fail to see how encouraging citizens to sue EPA -- by providing litigation costs, attorney and expert witness fees -- will improve EPA's ability to regulate pesticides or protect the public health. Unlike other environmental statutes, the number and types of suits which could be brought against EPA or specialty pesticide producers and users under FIFRA (or FFDCA) are staggering. Instead of reviewing pesticides, valuable EPA resources (possibly including industry generated program fees) will be spent defending vexatious litigation. Regulatory expertise is at EPA; let's keep it where it belongs.

Integrated Pest Management (IPM)

RISE supports the objectives of the modern pest management strategies generally referred to as IPM. In fact, our members are urging, and a large percentage of our customers are already utilizing many of those techniques. However, by intentionally failing to specifically list synthetic chemicals as a component of IPM, and by directing Federal agencies to adopt and promote IPM through procurement and otherwise, H.R. 4329 creates an illegitimate legislative preference for biological controls. This distinction is without merit or scientific basis, and ignores the realities and needs of both agricultural and non-agricultural pesticide use markets. It is an insult to the

entire registration program that H.R. 4329 uses both policy and Federal agency programs to discriminate against the very class of products which EPA registers for use under FIFRA.

CONCLUSION

RISE is committed to improving the programs under which our members products are registered and used. We support improvements designed to speed the introduction of new products to the market, utilize sound science, and promote the safe and appropriate use of our products. The bills offered by the Administration attempt wholesale revision where simple fixes would suffice. They fail to coordinate with existing authority, and fail to comprehend the needs of the specialty pesticide industry. For those reasons, RISE supports H.R. 1627, the "Food Quality Protection Act of 1993."

**Testimony of
Norman Goldenberg
On Behalf of The
National Pest Control Association**

Mr. Chairman and members of the Subcommittee, thank you for allowing me to testify today on behalf of the National Pest Control Association (NPCA). We appreciate the opportunity to share with you the views of our industry.

My name is Norman Goldenberg. I am the Vice-President of Government Affairs for Terminix International and TruGreen ♦ Chemlawn, which is headquartered in Memphis, Tennessee. I am also a past President of the NPCA. I am accompanied this morning by Bob Rosenberg, NPCA's Director of Government Affairs.

NPCA is the national trade association representing approximately 10,000 professional pest control companies that engage in the business of providing structural, institutional, and industrial pest control services. Services are rendered to homes, restaurants, hospitals, food processing plants, offices, schools, and other public buildings to control pests such as ants, cockroaches, termites, ticks, rats, mice, and fleas.

Such pests are directly responsible for a variety of diseases that threaten the public's health and well-being, including salmonella, hantavirus, rabies, Lyme Disease, and Rocky Mountain Spotted Fever. In addition, termites and other wood destroying organisms cause more than \$2.5 billion worth of damage annually to wood structures, more than fires, floods, and other natural disasters combined.

Obviously, urban pests are extremely disruptive and we applaud the Subcommittee's efforts to deal with the issue of reforming and improving America's pesticide laws. Specifically, we would like to address some of the provisions of H.R. 4329, and also discuss several topics we believe the legislation does not adequately cover.

I. Congress needs to enact tougher certification and training standards for commercial pesticide applicators

The first issue NPCA believes Congress must address as it moves to amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is to toughen the federal standards for certification and training of commercial pesticide applicators.

Currently, federal law requires only applicators of restricted use pesticides to be certified. If, however, a person applies a restricted use product under the direct supervision of a certified applicator, that person is not required to be certified. Furthermore, in-house pesticide applicators such as custodians, groundskeepers and building managers are not subject to any federal requirements at all, unless they apply restricted use products. In most cases, these do-it-yourselfers are applying products which contain the same active ingredients and the same concentration levels and dilution rates as the products used by certified and licensed professional pest control companies.

One of NPCA's biggest nightmares is that a custodian, not certified or trained in the safe use of pesticides, will expose school children, teachers, and others to harmful substances. Sadly, this scenario is not just a nightmare.

And because most custodians are not knowledgeable about the use of pesticides, pest identification or harborage, and other Integrated Pest Management (IPM) techniques, there is no reason to believe that we have seen the last of these types of incidents.

NPCA believes the minimum certification and training standards are woefully inadequate and need to be upgraded and we also believe that anyone who applies pesticides in public buildings should be subject to these requirements. Many states have adopted much tougher certification and training requirements. It is time for the federal government to also adopt more comprehensive regulations.

Specifically, we believe that applicators of any pesticide, other than homeowners, should be subject to federal training standards and the definition of commercial applicators should be broadened to include in-house personnel who apply pesticides to schools, hospitals, apartments, offices, and other buildings frequented by the public, though we support exempting individuals whose jobs require the use of anti-microbials. Since most states already have the agencies and the personnel to train and certify applicators and the fees are paid for by the industry, these requirements would place no additional financial mandates upon the states. We further believe that persons operating under the direct supervision of a

commercial applicator should undergo mandatory verifiable training and be registered by state pesticide regulatory agencies.

Bills were introduced in the 101st and 102nd sessions of Congress which would have achieved these goals. Senator Lugar's "Pesticide Safety Improvement Act of 1990" (S. 2490) in the 101st Congress and Mr. Rose's "Pesticide Safety Improvement Act of 1991" (H.R. 3742) in the 102nd Congress both contained language that would have significantly improved the certification and training provisions of FIFRA. In fact, this Subcommittee approved the language when it marked up H.R. 3742 in 1992. When this Subcommittee considers FIFRA legislation, we urge you to again adopt language that rectifies this glaring deficit in the federal pesticide regulatory program.

II. Citizen Suits Will Adversely Affect Pest Control Businesses and Are Not Necessary

The second issue I would like to discuss is citizen suits. Currently, 50 state governments and the Environmental Protection Agency (EPA) oversee the structural pest control industry and are responsible for investigating any alleged violations of FIFRA and other statutes relevant to the pest control industry.

Adding a section on citizen suits seems to be an advertisement encouraging unfounded claims of wrongdoing against pest control operators. This additional threat will greatly burden pest control businesses.

Just as it has the medical and aviation industries, the threat of being subjected to a multi-million dollar lawsuit could destroy many pest control operations. Regardless of whether any damage payments are made or consent agreements reached, skyrocketing insurance costs and lawyers fees are enough to put a pest control operator out of business.

Certainly, any citizen who wishes to file suit against a member of the pest control or chemical industry should be able to do so. We do not wish to restrict this right. In fact, we believe any pest control operator or chemical manufacturing company that has knowingly jeopardized the public's well-being should be forced to compensate the affected parties.

However, in light of the Senate's passage of legislation providing the aviation industry with tort relief, and the fact that more than 300 House members are cosponsoring companion legislation, we believe Congress is fully aware of the impact that frivolous litigation has had on our nation's businesses. In fact, the bill's chief sponsor and 16 of its cosponsors sit on this Subcommittee. Thus, we believe H.R. 4329's section on citizen suits sends a mixed signal to pest control operators and we ask that this language be removed from the bill.

III. Civil Penalties Should Not Impose an Unreasonable and Disproportionate Hardship on Pest Control Businesses.

I would also like to take this opportunity to comment on the additional civil penalty authority H.R. 4329 grants to EPA. The Administration's bill would increase the existing maximum

penalty of \$5,000 to \$25,000 per day for each violation of FIFRA. This applies to registrants, applicants for registration, producers, sellers, distributors, commercial applicators, and farmers.

While NPCA agrees that violators of FIFRA should certainly be punished, imposing daily civil penalties seems harsh and unreasonable. Instead of counting each day the violator is not in compliance as another infraction, we believe the violator should be given a realistic time period to comply before another penalty is assessed.

Unlike pesticide manufacturers, formulators and distributors, the overwhelming majority of commercial applicator companies are small businesses that employ fewer than 10 employees. A \$25,000 civil penalty could prove devastating for a typical pest control company, forcing the elimination of jobs, closing of pest control businesses, and possible bankruptcy.

Therefore, NPCA feels that larger businesses such as registrants or formulators should be subject to one civil penalty and farmers and commercial applicators should be subject to another; not exceeding \$5,000 per offense.

IV. Congress Needs to Take Steps to Protect Industry From the Loss of Products That Protect the American Public From Disease Carrying Pests

When Congress last amended FIFRA in 1988, it required the EPA to reregister all pesticides that were originally registered prior to 1984, including pesticides that are used for the protection of public health. The costs of reregistering pesticides used in institutional and

public health pest management programs can be very high and the volume of sales very low. In many instances, it simply is not economically viable to reregister a "minor-use" public health pesticide. We are concerned that this already has and will further result in the loss of some of the important tools which our industry uses to combat pests which pose a threat to public health.

Early last year, Mr. Dooley and other members of this Subcommittee introduced H.R. 1867, the "Public Health Pesticides Protection Act of 1993," which ensures that products vital to the protection of public health are not lost simply due to the expense of their being reregistered. We support H.R. 1867 and urge you to include its provisions in any FIFRA legislation adopted by this Subcommittee.

V. Once and For All, Congress Needs to Reaffirm the Strong Partnership Between the State and Federal Governments

In June of 1991, the United States Supreme Court overturned the long-standing belief that FIFRA preempted the regulation of pesticides by local units of government or, in other words, the court paved a path to regulatory chaos by permitting the 83,000 local units of government in the United States to each adopt its own set of confusing, contradictory and overlapping regulations. This decision has potentially disastrous consequences for pest control companies, the consumers who want and need their services, and the individuals charged with regulating this activity.

Companies in the pest control, lawn care, tree care businesses and other industries which may apply pesticides in non-agricultural settings vary in size from large companies, like mine, to very small companies, the proverbial mom and pop operations. In fact, the overwhelming majority of companies represented by NPCA are small businesses, each employing a small handful of people.

Big or small, however, we have one thing in common. Unlike many other businesses which may operate from a stationary facility in a single community, pest control companies typically provide service to customers in dozens or hundreds of communities. If each of those communities adopted its own licensing, training, testing, certification, insurance and sign posting requirements the result would be an unmanageable regulatory patchwork. Worse yet, if each community required permits prior to some treatments, outlawed certain products or prescribed different times of day during which applications can be made, the consequences for my industry and the American public would be catastrophic. Costs will go up, our ability to respond to pest problems which pose a threat to public health will be constrained and ironically, more pesticides will be applied by untrained and unregulated do-it-yourselfers, resulting in a greater misuse of pesticides.

I do not wish to give this Subcommittee a mistaken impression that we oppose the regulation of our industry. To the contrary, we vigorously support responsible regulation of our industry by the state and federal governments which have the ability and technical expertise to competently handle this important task. A careful reading of the legislative history of this

issue should draw you to the conclusion that this clearly was the intention of those who originally drafted the law. To accomplish this, we urge this Subcommittee to adopt an amendment to FIFRA, like H.R. 3850 drafted in 1992, which had over 100 cosponsors, to restore the traditional effective, strong regulatory partnership between the state and federal governments.

Conclusion

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to present testimony on these important issues. We look forward to working with the Subcommittee to improve our nation's pesticide laws.

Testimony
The Professional Lawn Care Association of America
Before the Subcommittee on Department Operations
and Nutrition Committee on Agriculture
June 15, 1994

The Professional Lawn Care Association of America (PLCAA) appreciates this opportunity to share its views on "The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Amendments of 1994", H.R. 4329. The legislation before us will significantly affect the landscape care industry and the following issues should be addressed and accounted for with any amendments to FIFRA.

Organized in 1979, PLCAA is the only international trade association representing an industry of over 6,000 landscape care companies in the United States and abroad. These companies range in size from small businesses, employing as few as one or two people, to large public corporations and franchise operations. Our industry provides services to residential and commercial customers which include fertilization and pest control, as well as mowing, maintenance, irrigation, aeration, seeding, landscaping, and ornamental and small tree care. PLCAA promotes professionalism in the industry, develops educational programs, recommends industry standards and serves as a leading voice in the landscape care industry. In fact, PLCAA has been a national leader in recommending standards and regulations which prevent the haphazard or unwarranted use of pesticides and insecticides. PLCAA members are vitally interested in improving many aspects of FIFRA so as to raise environmental consciousness and adherence to existing and new legislative mandates. Some of these issues are not currently addressed in H.R. 4329. Our testimony will address the following issues:

- (1) Mandating the types of standards already used by PLCAA for certification and training of pesticide applicators; increased education of homeowner "do-it-yourselfers;" and support of Integrated Pest Management (IPM);
- (2) PLCAA's proposed amendments to FIFRA that provide for uniform posting in every state when landscape care applications are made;
- (3) PLCAA's opposition to adding additional and unnecessary citizen legal remedies;

- (4) PLCAA's opposition to additional and unnecessary EPA civil penalty authority for violations by commercial applicators;
- (5) PLCAA's support of preemption of local regulation of pesticide use under FIFRA to provide for a uniform national standard.

Certification and Training for Pesticide Applicators

The proper training of employees is one of the most important factors in providing responsible landscape care services to the public. PLCAA plays an important roll for its members and others by sponsoring educational seminars and developing and disseminating training materials for the industry internally and through the media.

PLCAA supports the current certification requirements for pesticide applicators under FIFRA, however, we believe should be tougher. Currently, FIFRA allows the application of restricted use pesticides by technicians who may or may not be trained, so long as the activity is performed under the direct supervision of certified applicators. A big loophole remains. The law also permits application of general-use products without any training or without the supervision of a certified applicator. Additionally, FIFRA does not require certification of "in-plant" workers, such as maintenance personnel. Taken together, these omissions leave significant gaps in current law.

With these concerns in mind, PLCAA recommends across the board certification and training requirements for pesticide applicators in H.R. 4329, precisely the same language as proposed in the Pesticide Improvements Act of 1991 (H.R. 3742).

These additions, if implemented, would raise the standards of our industry by requiring state-approved training for all commercial pesticide applicators regardless of whether the pesticides applied are classified for general or restricted use.

PLCAA further recommends that the mandated training be provided through approved instructors from the USDA Extension Service, state-approved consulting firms and/or industry associations, the state lead agency, or licensed applicator firms.

Further, PLCAA supports the requirement that "in-plant" personnel and those they supervise receive verifiable state-approved training before applying restricted-use pesticides. Additionally, this requirement should be extended to include the application of any general-use pesticide by any "in-plant" applicator.

The need for training and knowledge to properly apply a pesticide should not be limited to restricted-use pesticides, which in fact represent a very small amount of the products applied.

We also support the training requirements for state enforcement personnel. This will ensure that state employees charged with monitoring compliance with applicable federal and state regulation are able to fully comprehend enforcement requirements.

PLCAA further supports the provisions of H.R. 4329 requiring that, all interested individuals be notified of the availability of instructional materials covering integrated pest management techniques upon request.

Finally, while PLCAA believes that the proposed training and certification requirements are essential to responsible landscape care services, our members are concerned that even with this new program, many of the non-commercial users of pesticides -- the homeowner or "do-it-yourselfer" -- often apply these products without sufficient information, instruction, or label comprehension. The Environmental Protection Agency's (EPA) 1990 National Home and Garden Pesticide Use Survey suggests that house hold pesticides "are not always used as carefully or effectively as they should be." EPA has stated that this survey provides "a basis for expanding outreach and educational programs on pesticide safety for consumers." According to the 1991-1992 National Gardening Survey, 62 percent of all U.S. households, or 58 million households, participated in do-it-yourself lawn care in 1991. Only 7 million households employed the services of certified and licensed professional landscape care operators. The committee may not be aware that the vast majority of the products used by professionals and do-it-yourselfers are the same; therefore, we recommend that Congress consider adopting a voluntary training program aimed at these non-professional users. The program could be coordinated by EPA or the USDA Extension Service, and implemented by state agencies in cooperation with the industry or it's trade associations.

By adding these important elements of training, we should be able to address some of the concerns posed in the National Academy of Science's report "Pesticides in the Diets of Infants and Children." If non-dietary exposure to treated lawns is a concern, why not ensure that all pesticide users be properly educated and trained? This also relates to my next issue.

National Regulation of Lawn Care Pesticide Applications

PLCAA has led the way in the reasonable and responsible regulation of landscape care applications. To that end, our members are prepared to work with Congress and other interested parties to ensure that any legislation ultimately adopted protects both human health and the environment, while at the same time accommodates the practicalities of providing lawn care services. PLCAA members believe that a nationwide standard will strengthen consumer confidence in the products and services associated with lawn care applications.

To go one step further in addressing the National Academy of Science's concerns, we recommend a standard for nationwide posting of signs when lawn care applications are made. Certainly the use of these signs by ALL pesticide users with a telephone information number listed, will help children avoid possible exposures. PLCAA's members have been a nationwide leader in promoting voluntary posting. This practice provides their customers, as well as the general public, with notice that an application has been made. It also provides the general public with a means of obtaining additional information about the application if so desired.

PLCAA supports a federal posting standard for all applications, whether professional or not, with dowels and signs provided by retail establishments for the "do-it-yourselfer" applicator. Standardizing this requirement to include the homeowner would provide consistent notice to the public of pesticide applications, as homeowners, as we have stated use primarily the same products as professional applicators, and, in fact perform about 85 percent of all landscape care applications.

PLCAA suggests the posting of a 4 x 5 inch sign at the primary point or points of entry to the property at the time of the actual application. The required use of these signs in 18 states has proven that the public easily identifies a 4 x 5 inch sign as a lawn marker and a notice that an application has taken place. The property owner or resident could remove the sign(s) the day following the application when an exposure risk has subsided. The marker notifies the public that an application was made sometime that day and to keep out of the treated area.

Content of Signs

PLCAA's position regarding the posting of signs, is as follows:

- o Signs should be 4" x 5" in size to take advantage of already exiting public standards, strengthened by six years of use.
- o The signs should state that a landscape application has taken place and care should be taken to avoid contact with the treated areas. PLCAA recommends the following language in not less then 18-point type: "LANDSCAPE CARE APPLICATION. PLEASE AVOID CONTACT."
- o Signs used by commercial applicators should bear the company name and telephone contact number as a means of accessing additional application information.
- o Lettering on signs should be in a color that contrasts with the background to assure visibility.
- o Signs for use by do-it-yourselfers should be required to be provided by retail establishments with instructions for their use.

Citizen Suits

PLCAA opposes the addition of provisions for citizen suits against commercial applicators. The Administration has previously stated that problems currently exist with inadequate enforcement of laws, such as SUPERFUND, because too many lawyers and lawsuits bog down the process. Why invite additional litigation when there is sufficient access in the existing legal process to assist citizens who have claims?

FIFRA requires states to ensure enforcement of state pesticide use regulations, and provides a formal referral process for EPA to require states to follow up on complaints.

We believe people have the right to file legitimate claims against commercial applicators. The current legal process operates effectively -- additional provisions would be superfluous.

Civil Judicial Enforcement

PLCAA opposes any provision that would extend the U.S. Environmental Protection Agency's civil penalty authority from \$5,000 to \$25,000 in fines for commercial applicators, farmers, and/or any other small business entities. Most commercial applicators are not in the same category as large industrial businesses and can ill afford being fined at the proposed level.

Without sufficient proof that increasing the fine amount on applicators will provide some societal benefit, we question whether it is completely arbitrary and unwarranted.

Preemption of Local Regulation of Pesticide Use

PLCAA believes that any comprehensive pesticide legislation must provide for a national standard, with preemption of local regulations, when necessary to allow commercial applicators to continue to conduct business in a responsible manner. It is PLCAA's position that regulation of pesticide use must be monitored and administered at the federal and state levels where the coordinated and technical expertise is available to render sound scientific judgements. The current checkerboard regulatory maze is extremely counter-productive.

PLCAA stands ready to assist this Subcommittee in developing proactive language toward the reasonable and responsible regulation of the landscape care and pesticide user industry.

Thank you for the opportunity to present these comments and recommendations. I'd be happy to answer any questions.

Statement of William Hazeltine, Ph.D., representing the American Mosquito Control Association, before the Department Operations and Nutrition Subcommittee of the House Agriculture Committee, concerning the Administration's proposed amendments to the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). For presentation June 15, 1994.

Mr Chairman and Members, thank you for the opportunity to present testimony about the Administration's proposed amendments to FIFRA, contained in H.R. 4329, particularly the impact these amendments will have on our ability to provide the best possible vector control. The issue, which is of concern to us, is the continuing loss and the absence of any new, effective pesticides to protect the health of the public we serve.

We protect health by the use of pesticides, and we need your help in being able to continue this service. Public Health uses of any pesticide is the direct result of a positive balance between the direct health benefits of that use, and any possible adverse effects on humans or the environment.

I have reviewed H.R. 4329 and while it considers some of our needs, it only considers help with defensive actions (=it provides some relief from risks of cancellation or suspension). It does not consider the need for a more streamlined and fast registration process for uses of new pesticides for health protection. We appreciate any help which the Administration wants to provide, but we feel it is necessary to suggest ways that any amendments to the Act can be made more workable and balanced.

H.R. 4329 considers public health pesticide uses specifically in the following places:

Page 33, lines 15-20. Consultation with Secretary of HHS on proposed cancellation or change in classification of a pesticide registered for a public health use, and an opportunity for comment.

Page 48, lines 19-23. Consultation with the Secretary of HHS regarding any proposed suspension of a pesticide registered for public health use.

Page 86 line 1 through page 88 line 6. Provides for consultation with the Secretary of HHS before suspension or cancellation of a pesticide registered for public health or health protection use, as a way to decide whether the potential benefits for public health or health protection purposes are of such significance

as to warrant a commitment by the Secretary of HHS to conduct or arrange for studies required by the Administrator of EPA, to support continued registration. It then outlines the mechanisms for such research and support.

There are at least 2 additional places where the consideration of public health use pesticides might have been appropriately considered:

Page 60, lines 5 through 11, neglects the impact of this action on the availability of public health use pesticides, and considers only the unnecessary dislocation of agricultural production. Note that the present standard for most registration actions is proposed to be changed in this Section of the Act titled Phaseout/Phasedown: The defined term "unreasonable adverse effects on the environment" is not used, and a new term is proposed on Page 59. lines 15 through 18 which reads "---use of the pesticide is reasonably likely to pose a significant risk to health or the environment".

The present standard, which is based on the term "unreasonable adverse effect on the environment" was adopted in 1972. This term is defined to require risk/benefit balancing, and is the basis for any present registration related action by EPA.

Page 71, lines 20 through 25, allows the Administrator to consult with the Secretary of Agriculture on issues of IPM, alternative pest management, and reduced pesticide use. This section also authorizes the secretary of Agriculture to enter into agreements for research, and seems intended to apply to all pesticide users, without limiting such activities to crop production.

Unless the clear provision for separate registration for new public health pesticides is included in any final Administration Bill these parts of H.R.4329 should be amended to include public health pesticides, as well as agricultural pesticides.

We also suggest that the well defined standard for any registration related action, using the term "unreasonable adverse effect on the environment", be retained, and that new different terms for similar standards be avoided.

The term "minor use" is defined on pages 82 and 83. This definition seems to add the substance of the definition originally found in the predecessor Bill for H.R. 967 (300,000 acres and 5 million dollars over 3 years) as well as the definition in H.R. 967 and H.R.1867 (economic

standards alone), but H.R. 4327 then adds conditions to the economic standards approach, to include either insufficient efficacious pesticides, the alternative pesticides are more risky to use, or the new product is necessary to manage resistance.

We prefer the simpler yet adequate definition which is found in the present version of H.R. 967 by de la Garza or the definition in H.R. 1867 by Dooley and Herger. Either one is sufficient to establish a workable standard.

The definition of a "Biological Pesticide" on page 68 includes the term "any organism that is a biological control agent". If this definition is adopted, it would require the registration of all biological control agents, before they could be used in pest control. In the case of mosquito control, we use mosquito fish extensively, and it would add an unnecessary burden on our operations if we had to have registration, labels and accepted directions for use on a barrel of fish which we might collect from one pond and move to another. Additional problems involve questions of who would be the registrant for these fish. Furthermore, any private property would be at risk of inspection by EPA if it had mosquito fish on it due to purely natural causes, in addition to any that were purposely planted for mosquito control.

We seriously doubt the wisdom or necessity of trying to bring biological control agents under EPA's pesticide registration authority.

If the Administration Bill is seriously considered for adoption in its present form, we hope that the Subcommittee will consider the major problems which we have identified. The most important amendment we see is the need to add the substantive provisions of H.R. 1867 to the end of Section 10 of the Administration's Bill. This would make it clear that when considering the registration, or reregistration, as well as any deregistration (cancellation or suspension) of a public health pesticide, the Administrator should conduct separate risk/benefit balancing for these pesticide uses, as part of the registration process, and also consult with the Secretary of HHS on the need for such health protection uses.

While our testimony has focused here on H.R. 4329, and ways to improve that Bill, it is important to understand that our problems and needs are not tied to any of the larger legislative alternatives before you, including the Administration Bill. A comprehensive Minor Use Bill, such as a joined H.R. 967 and H.R. 1867 is one way to provide for our needs. We will support any bill that addresses the consideration of Public Health Pesticides, as a separate class for registration, as contained in H.R. 1867.

Our needs can be addressed in a number of ways, and we ask this Subcommittee to please include some provision for a separate class of registration for Public Health Pesticides in whatever Bill you approve and send on to the full Committee.

We thank the members and staff of this Subcommittee for your continued attention and support of the needs for effective, available and affordable pesticides for use in protecting the health of the public from diseases and annoyance. We need your help today, because another year's delay in relief will further reduce our ability to provide necessary control for our constituents, which are also your constituents

(Attachment follows:)

WILLIAM HAZELTINE Ph.D., B.C.E.**Environmental Consultant****119 Flying Cloud Dr.
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Call for FAX connection**

April 30, 1993

Revised May 27, 1993

MOSQUITOES, DISEASE AND ENOANGERED SPECIES**Introduction:**

There is a traditional belief in our society that pesticides are detrimental to wildlife. This belief is the result of many factors, but primarily it is because of the alliance of Sport Hunters, Wildlife and Environmental organizations. This belief is also the secondary result of the folklore which is being taught as scientific fact in our Elementary educational system.

The idea that pesticides are not natural, and therefore "they must be detrimental to nature or wildlife" is the non-logic being fostered to further this belief.

Yet pesticides were developed to control pests--those organisms which eat crops, damage health, or are in competition with people for living space. Within this concept, wildlife is in large part a food crop, as sportsmen (hunters or fishermen) tell us, and as such, wildlife for sport harvest should be protected from pests which reduce the yield or harvest.

Endangered Species as well as plentiful plant and animal species of "wildlife", are subject to attack by pests, just like any other organism. Endangered or threatened wildlife do not escape predators and parasites, which eat on or otherwise adversely impact them, the same way these predators and parasites impact any other organism.

Present evidence shows that at least one species of bird is extremely rare, and may yet become extinct, due to a virus disease which is only possible when mosquitoes carry or vector the virus from bird to bird. Kangaroo rats, while not as rare, are subject to other viruses that mosquitoes carry from wild birds to them. As more research is done, the expectation is that there will be many more species of endangered animals that will be found to be harmed by similar insect vectored viruses and other disease organisms.

Plants, whether rare or plentiful, are eaten by insects, and other animal species in the "food web", but only humans are expected to know which species are so rare that they should not be eaten or harmed. The use of pesticides to protect rare plants from predation would seem

appropriate, the same way we use pesticides to protect and increase the yield of plants for human or livestock consumption.

The Endangered Species Act calls for "Conservation" of rare species, which means doing whatever is necessary to increase their numbers. Surely protecting those rare species from disease and predation is appropriate, yet there is a strong prejudice against such protection, if it involves the use of pesticides or even alteration of wetlands. Such is the dilemma.

Origin of the Problem:

The years 1961-62 marked the first major outcry against the use of pesticides. Popular fiction told stories of birds dying in tremors, after ingesting food containing a popularly used pesticide. There had been isolated stories of wildlife "suffering" before that time, but after the Book Silent Spring, the stories were extensive. Many Organizations sprung up to build on the anti-pesticide feelings which they themselves helped to create. The "Scientific" leaders of these Tax Exempt Organizations even wrote their own literature; much of which was published in newspapers or marginally credible "Scientific Journals."

There were even incidents of citation webs, where author A suggested something might be correlated with some event; author B would cite author A to give the correlation support, then author A would cite B as having concluded that the event was fact. Remember that correlation does not prove cause and effect; it only says two events have occurred at the same time or in the same place.

There were some cases where the data was stretched to try and make it fit a conclusion which was not supported by the evidence. In short, science was abused for the sake of winning some public relations achievement. In science, the "whole truth concept" is supposed to be met at all times. Science is not a contest where different experts tell their own side or belief, with the public left to decide which one of these people is really an expert, or which one is believable.

During Earth Days (April 22, 1972 and later) the public and particularly students at colleges were subjected to all sorts of situations where they could demonstrate their beliefs, and do something about the environmental degradation alleged to be caused by chemicals and other causes. The movement was really aimed at stopping technology, with no thought about the benefits these technologies had produced. The affluent students were expected to demonstrate their faith in a "cause."

As Sol. Alinsky, the radical organizer said in one of

his self-help books, Rules for Radicals, "If the ends don't justify the means, what the hell does?"

Mosquito Disease transmission:

In order to understand the issue of damage to animals by viruses or other disease causing organisms carried or vectored by insects, it is necessary to understand some details of how such diseases organisms are transmitted.

In the case of malaria, the protozoan parasites must go through alternate hosts, in order to have natural transmission. The organism must have a vertebrate host and then a mosquito host or vector, and then go back into a vertebrate host. A necessary part of the life cycle occurs in each host. There is bird malaria, as well as malaria in mammals, and each kind has separate mosquito vectors and each kind has unique Protozoan Parasites.

Some kinds of serious virus diseases, such as many kinds of Encephalitis (or Encephalomyelitis) require an insect to pick up the virus from a host, amplify it, and then pass the virus on to whatever host it feeds on next. Many of the human and animal "encephalitis"-diseases require susceptible vertebrate endemic or reservoir hosts to develop a viremia, and to have these viruses available to insects before that reservoir host animal develops antibodies to the virus, and thus becomes non-infective. Human or livestock disease can occur when an infected mosquito feeds on a person or other animal that is susceptible to the virus.

At one time, before the development of the vaccine, Poliomyelitis was thought to be mechanically transmitted by house flies. This did not involve a specific vector, but was thought to be mechanically carried by anything which would feed on body fluids from a sick host, and then carry the virus to a new host.

The kinds of encephalitis which the public has come to understand often goes by the name of the place where it was first found. For example, St. Louis Encephalitis (SLE) was first isolated from St Louis, but it is widespread over broad areas of North America. Just a few years ago, an epidemic of SLE occurred near Disney World in Florida, and caused widespread illness, death and fear sufficient to cause severe economic disruption of the tourist trade.

Other kinds of encephalitis which occasionally occur in the United States include Western Equine (severe in horses as well as people) Eastern Equine (also severe in horses as well as people), and LaCrosse encephalitis which is insidious by causing delayed neurological effects. There are other potentially serious insect vectored virus diseases, such as Japanese B Encephalitis, California

Encephalitis, Venezuelan Equine Encephalitis, Dengue and Dengue Hemorrhagic fever, and Yellow Fever. All of these are vectored by insects, primarily mosquitoes. Other similar, but as yet unidentified diseases are possible, because there are new virus antibodies being found which are not yet associated with human or animal diseases. Even mosquitoes found in snow-melt pools in mountainous areas of California have been found to carry viruses of unknown disease significance.

The usual cycle of many of these diseases of humans and other animals involves wild birds. These birds serve as the endemic or amplifying host, where the virus is either active all year round or possibly carried in by a migrating host, often another bird species. There are less common endemic cycles involving Jackrabbits, for example, but the most common cycle appears to be in local wild birds. Current evidence suggests that some of the migratory wetland birds, such as Herrons and similar bird species, are involved in longer distance transport and importation of the viruses, which may have died out after the last mosquito breeding season.

Wetlands are an obvious breeding place for mosquito vectors, and thus they have a high risk of diseases associated with them, whether they are new or old wetlands. Eastern Equine Encephalitis (EEE) transmission may involve two species of mosquitoes, one for the endemic cycle and another for the epidemic cycle in which humans, and horses can be infected. In the case of endangered birds, the cycle is direct, with the degree of mortality depending on the severity of the viremia produced and whether the host dies before it can recover and produce antibodies for immunity to later infections. Pheasant Farmers in the midwest have experienced severe epidemics in their pen reared birds from EEE virus.

Bird Malaria is apparently not a particular problem in Game species, which seem to occupy most of the Wildlife Biologist's attention.

Virus Diseases in Endangered Species:

The best example of severe disease and death of an Endangered Species caused by a mosquito vectored virus disease is in Whooping Cranes. The captive breeding program at the Federal Government's Pautuxent Wildlife Refuge in Maryland is trying to produce enough of these birds to reintroduce them into the wild. In 1984, 7 of 23 birds died from EEE at the station, and 7 others had naturally produced antibodies. The remaining live birds were inoculated with an experimental vaccine. This apparently was successful, but any of the birds which are produced in the wild, even from vaccinated parent birds, will be susceptible to this virus. The introduction plan calls for putting these birds

into an area which is known for having EEE epidemic conditions in the past.

With the discovery of the extreme susceptibility of Whooping Cranes to EEE, a plausible explanation for the near extinction of these birds now exists. There are two major migration routes used by these birds in the past; one was from Canada to the Southeastern U.S., and the other was from Canada to Texas. The natural range for EEE as we know it is from the central Midwest to New England, south to the Southeastern U.S. This area seems to include a large part of the migration routes of these birds.

Sand Hill Cranes are a related species which is susceptible to EEE virus infection, but apparently, this species does not experience the extremely high mortality seen in Whooping Cranes. Even Bald Eagles held at the Pautextent Station have been infected and show antibodies to EEE.

It is obvious that Cranes in nature can not be easily captured and vaccinated, which leaves mosquito control as the best way to protect these scarce birds from EEE.

At the same time the Pautextent Station (in Maryland) was experiencing its epidemic and up to today, the National Park Service has refused to allow vaccination of the wild horses on Assateague Island in Eastern Maryland. EEE is a severe disease of unvaccinated horses, and results in a day or so of symptoms before the horses usually die. A sick horse lies on its side and tries to run, but only succeeds in digging an arched area where its hoofs scrape the ground. The reason given by the Park Service for not allowing mosquito control to protect these horses is the NPS' goal of getting rid of the horses on the island, so it can go back to its natural pre-human condition. The horses were introduced by man.

Another discovery about encephalitis was made, as a result of laboratory experiments on Kangaroo Rats, before the populations were listed as endangered. The University of California Virus Disease Research Station at Bakersfield, California used 2 species of local Kangaroo Rats as test animals. The research was aimed at finding the endemic and epidemic species of animals involved in transmission of the two virus strains which had been epidemic in California. The "Fresno" Kangaroo Rat was extremely susceptible to Western Equine Encephalomyelitis (WEE) and the "Heermann" Kangaroo Rat was also susceptible to the virus disease, but not quite as severely.

After this research was completed, there were 5 species of these Rats listed by the Federal Government as endangered. California lists 12 species or subspecies, 7 of which are subspecies of the two species tested earlier by

the University workers.

Sanctuaries which have been created for these rats include the Salt Bush type of habitat which the Rats like. The kind of land in the Southern San Joaquin where Salt Bush is found is not good agricultural land, and so Refuges have been established. These Refuges are often surrounded by Duck Hunting Clubs, which have created "wetlands" for ducks, but which at the same time have created ideal mosquito breeding habitat. These wetlands are also attractive areas for wild birds which could serve as transporters of the virus in addition to serving as the endemic hosts, to increase the amount of virus. With the high degree of susceptibility of these Kangaroo Rats to WEE, it is a wonder they have not been wiped out in these Refuges. In other parts of the Valley where the virus occurs periodically at epidemic levels, there is risk to these Rats as well, but at a possibly reduced level.

The University research on Human and other animal encephalitis diseases, and the viruses which can cause them, did not particularly consider wild animal survival. The disease research was directed toward human and horse cases, and disease suppression. The data on Rats and other animals was only salvaged from the information presented in the researcher's studies. A review of only two studies showed that antibodies were present for WEE or SLE in Tricolored Blackbirds, Harvest Mice, Antelope Ground Squirrels, and Cotton Rats, as well as in Kangaroo Rats. All of these species, or closely related species are on the Federal Endangered Species list, or the California List. The same paper which reported the Whooping Crane problems reported finding antibodies to EEE viruse in Bald Eagles kept at the station in Maryland.

The Bluetongue virus in Big Horned Sheep is vectored by Culicoides Gnats, and this same disease is prevalent in Deer. Entire populations of these sheep have been exterminated by this disease, yet no effort has been made to vaccinate the sheep or to control the Gnat vectors. This lack of disease control has occurred, despite the tremendous costs of trying to reestablish colonizing Sheep populations. Building "exclusion fences" and protection from other adverse impacts has been practiced, while control of the vector has been ignored.

As far as I know, there is no active program to collect and test blood for virus antibodies from other bird or mammal species which are on the Endangered Species List, or are active candidates for listing. A prudent person should want to have this kind of data, because the Endangered Species Act mandates that all Agencies of the Federal Government are supposed to do everything possible to protect and even to increase all Endangered Species.

Mosquito Control Perspective:

The anti-pesticide movement and the wetland restoration promoters together have fostered an attitude in the Federal and State Governments which is a serious detriment to mosquito control. Not only do Humans suffer because of this attitude, but some Endangered Species are suffering from it as well. The Federal EPA has a strong bias against reregistration of any pesticide until a whole series of safety studies are completed and submitted to them for review. In the mean time, this Agency neglects its Legislatively imposed requirement which mandates a Risk/Benefit balancing. The present attitude of the Agency seems opposed to accepting a small insignificant risk, in order to allow the benefit of Human Health Protection. The Mandate to do everything necessary to protect the continued existence of Endangered Species, such as encouraging the registration of effective pesticides to control the mosquito vectors of virus diseases which can kill these Endangered Species is apparently completely overlooked as well.

Even the U.S. Department of Interior and its Fish and Wildlife Service have been leading opponents of mosquito control on their Refuges. They claim a concern for Endangered and Game species, as well as common wildlife, yet when these species may be directly effected by mosquito vectored diseases, or they may serve as endemic hosts for these virus diseases of people and wildlife, they adopt an attitude of indifference.

One Refuge Management Person said that flying adult insects were the food for a California listed bird on his refuge, and therefore anything that reduced the adult insects, such as chemical mosquito control on the Refuge would not be allowed under most conditions. This kind of attitude must change.

If the Endangered Species Act mandates protection of Endangered Species, then the Agencies of the Federal Government should join with Organized Mosquito Control to expedite reregistration of pesticides, and to work to remove the other roadblocks to the beneficial use of pesticides to protect Endangered Species.

The traditional beliefs that pesticides are detrimental to wildlife and are not "natural" are actually contributing to the loss of animals which have been declared as endangered. These anti-pesticide beliefs need to be replaced with an understanding of the positive benefits which pesticides can provide in protecting man's well being, as well as in protecting endangered species.

**TESTIMONY OF DAVID L. KARMOL
REPRESENTING THE
NATIONAL SPA AND POOL INSTITUTE
ON H.R. 4329**

**"TO AMEND THE FEDERAL INSECTICIDE FUNGICIDE, AND RODENTICIDE ACT,
AND FOR OTHER PURPOSES"**

JUNE 15, 1994

**U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON AGRICULTURE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION**

Good morning, Mr. Chairman and members of the subcommittee. I appreciate the invitation to appear before you today on behalf of the National Spa and Pool Institute, to discuss this important legislation.

BACKGROUND

The National Spa and Pool Institute (NSPI) is the national trade association of the pool and spa industry, with over 4,400 members involved in all segments of the industry, including: manufacture of pools, spas, and related equipment and chemicals; construction and reconstruction of pools, spas, and water features; wholesale and retail distribution of pools, spas, and related equipment and chemicals; and servicing of pools and spas.

NSPI provides a range of services to its members including development of voluntary construction standards for pools and spas; a nationally recognized education program to train and certify pool service technicians at three levels of competence; an extensive program of consumer education on water safety in cooperation with the National Safety Council, the American Red Cross, and the Consumer Safety Product Safety Commission; and an array of services such as insurance, an international trade show, industry promotion and technical services.

NSPI is the publisher of five American National Standards for various types of swimming pools and spas, with an additional standard pending. NSPI standards are the internationally recognized standards for the design and construction of all non-competition pools and spas.

NSPI is an international organization, with 80 chapters covering all fifty states, and a Canadian affiliate, NSPI of Canada. The Institute operates with a committee structure, utilizing voluntary experts drawn from the industry working with paid staff to develop policy positions on issues of common industry interest.

NSPI is involved in all aspects of pool chemical issues, including safety. It produces a series of consumer brochures describing proper chemical handling and use, and includes course material and instruction on chemical handling and safety in its standards, educational seminars and certification programs.

BACKGROUND ON POOL CHEMICALS

NSPI believes at the outset that it is important to understand what chemicals are used in the sanitizing and disinfecting of pools and spas, and whether those chemicals are classified as restricted use or general use pesticides under FIFRA.

Pool chemicals generally fall into several distinct categories including: balancers or stabilizers to maintain proper pH and alkalinity; mineral additives to maintain proper levels of mineral substances in water; clarifiers and flocculants which help collect suspended particulates; and disinfectants and algicides which destroy bacteria and inhibit pool and spa algae. Only the latter two types of products, disinfectants and algicides, are pesticides, and are regulated as such by the EPA.

With the exception of gaseous chlorine delivered in pressurized cylinders, all chemicals used in treating pool and spa water are available both to pool servicing firms and to the general public directly. No substance now approved for use in the normal servicing of pools is listed as a restricted use pesticide.

HOW FIFRA AFFECTS THE POOL AND SPA INDUSTRY

FIFRA is sweeping legislation, which regulates all pesticides to some degree, based on their risks to man and the environment. Some pesticides are banned entirely from production and use, other "restricted use" pesticides may be applied only by "certified applicators," and many, more common pesticides are required to be labeled for proper use and application by consumers.

All forms of chlorine and bromine compounds used for pool disinfection, as well as all algicides and some other pool additives, are classified by the EPA as "general use" pesticides, under FIFRA. "General use" pesticides, as defined by the Congress in the initial FIFRA legislation, are pesticides which pose little or no risk to man or the environment, when used according to label instructions. General use pesticides are sold over-the-counter to the general public. In fact, most pool chemicals are purchased and applied by pool and spa owners. The application of these chemicals is a simple matter of adding a certain number of pounds, or ounces, of the chemical for every ten thousand gallons of water in the pool, or ounces per hundred gallons in the case of a spa.

The regulatory scheme of FIFRA currently requires states to administer programs to register and certify applicators of restricted use pesticides. As introduced, HR 4329 would change this requirement, by expanding the definition of a commercial applicator to "one who applies any pesticide for hire as a principal part of the business or work of the person." (emphasis added)

As applied to the pool and spa industry, this would require that all pool service personnel, summer lifeguards, and community pool operators, many of whom are temporary employees hired for the swimming season, to be registered and certified by the state. Each employee would be required to attend and pass a state-approved comprehensive pesticide training course, including the identification of various rodents, insects and fungi, and the selection of the proper pest control chemical or technique. Almost none of the training required by most states has any relevance to the proper treatment of pool water, which involves maintaining a proper pH level, and a proper level of free chlorine or bromine.

Today, many industry employees are graduates of the National Spa and Pool Institute training program, and are known as Tech I, Tech II or Certified. Over 2,000 pool service personnel have earned one of these designations since the program began in 1989. In addition, most state health departments impose requirements on pool operators, requiring them to meet specific knowledge standards relating to proper pool water treatment.

OUR AMENDMENT

We propose an amendment to H.R. 4329, which exempts those who apply general use pesticides solely for the purpose of cleaning, sanitizing, disinfecting, painting or for use in construction or renovation. This amendment does not exempt any persons currently regulated under FIFRA; it simply continues their current exemption from the registration and certification requirements, as long as they are using only general use pesticides in their work. It allows the pool and spa industry to continue the employment of some 25,000 individuals in the pool service business, under current regulations and requirements. The proposed amendment follows this statement.

EPA POSITION

We have met with representatives of the U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. They have told us that it was not the intention of the agency to include pool service within the commercial applicator category as amended by H.R. 4329. We have requested a written statement of this position, and will share the response with the committee when it is received

MORE INFORMATION

The National Spa and Pool Institute is available to answer questions about this issue or other questions regarding our industry. Please contact David Karmol, at NSPI in Alexandria, Virginia at (703) 838-0083 or our outside counsel, Richard Bliss in Washington, DC at (202) 337-6008

(Attachment follows:)

**"TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE,
AND RODENTICIDE ACT, AND FOR OTHER PURPOSES"**

H.R. 4329

PROPOSED LEGISLATIVE AMENDMENTS TO H.R. 4329

**PREPARED BY
NATIONAL SPA AND POOL INSTITUTE**

"SEC. 17. ENFORCEMENT"

"(e) APPLICATOR -

"(2) COMMERCIAL APPLICATOR. -

At line 6 & 7 (page 102) by inserting the following clause after "except as provided in"

SUBPARAGRAPHS (3) AND (4),

At line 19 (page 102) by inserting the following subparagraph

(3) "COMMERCIAL APPLICATOR" SHALL NOT INCLUDE ANY PERSON WHO USES OR SUPERVISES THE USE OF ANY PESTICIDE WHICH IS CLASSIFIED FOR GENERAL USE SOLELY FOR THE PURPOSE OF CLEANING, SANITIZING, DISINFECTING, PAINTING OR FOR USE IN CONSTRUCTION OR RENOVATION.

Insert new numbers for the succeeding subparagraphs

June 15, 1994

My name is Barbara Baughman, Newberry, South Carolina. I am Co-Legislative Chairman for National WIFE (Women Involved in Farm Economics) an organization of farm women in 25 states.

Thank you for the permission to address the proposed Pesticide and Food Safety Reform Legislation via written testimony.

WIFE's concerns: The proposed Pesticide and Food Safety Reform Legislation eliminates risk/benefit considerations, establishes an arbitrary and overly restrictive risk standard, sets an unworkable dual tolerance system, and would phase out the use of pesticides without the procedural protections and external scientific review guaranteed under the cancellation process, and FDA would be granted new recall, embargo and civil penalty authority for pesticide tolerance violations.

WIFE encourages the use of proven data as opposed to human emotions in regulations that govern our industry.

We request that EPA be permitted to remove a farm chemical from the market only after positive proof has been established that there is a health hazard when used as labeled.

We request that restrictive standards of the Delaney Clause related to food safety laws be revised to be more acceptable to producers and still protect consumers.

We request the litigation/enforcement concept be dropped. While not allowed against an agricultural producer, the encouragement of civil suits will always have the "trickle down" effect to still lock the farm gate.

WIFE requests that before instituting any new rules and regulations affecting the farmer, the government analyze the benefits as compared to jobs lost, food production capacity eliminated, and damage to the farmers.

"The quickest way to bring America to her knees is to destroy her ability to produce her food!"

Thank you for your time.

Barbara Baughman

Barbara Baughman
Co-Legislative Chairman for WIFE
(Women Involved in Farm Economics)



*Natural Resources
Defense Council*

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TESTIMONY OF ALBERT H. MEYERHOFF
AND JENNIFER CURTIS

on behalf of
Natural Resources Defense Council

before the

HOUSE AGRICULTURE COMMITTEE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

Hearings on Legislation to Amend
THE FEDERAL FOOD DRUG AND COSMETIC ACT and
FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

June 10, 1994

I. Introduction

I am Albert H. Meyerhoff, Senior Attorney with the Natural Resources Defense Council (NRDC), a national nonprofit environmental organization dedicated to protecting the public health and the environment with over 170,000 members. For more than two decades, NRDC has been actively involved in the host of issues presented by the increasing use of pesticides and their impact on the environment. I appreciate this opportunity to testify today regarding legislation proposed by the Clinton Administration to amend federal pesticide laws. Before addressing the Administration bill, however, I would like to briefly summarize the Administration plans to obey the law as written.

II. The Delaney Clause: A Clear and Present Mandate

As one of her first acts following confirmation as EPA Administrator on February 2, 1993 Carol Browner indicated that one of her top priorities was to achieve comprehensive reform of the nation's antiquated food safety laws. However, as a condition of that reform, which included replacement of the Delaney Clause, she indicated that the pesticide laws should be amended only if to do so would "give the public more protection, not less." (New York Times, February 1, 1993 at p. 1.)

Absent legislation, and unlike its predecessor, this Administration has repeatedly emphasized its commitment to comply with and fully implement existing law, including the Delaney Clause. Thus, at a September joint hearing of the Senate Labor

and Human Resources Committee and the House Energy and Commerce Committee, Subcommittee on Health and the Environment, Administrator Browner stated EPA's intent to comply with the precedent established in Les v. Reilly and implement Delaney in a timely fashion. (Hearing on Legislation to Amend the Food, Drug and Cosmetic Act, Washington DC, September 21, 1993.)

At an October 1993 House Government Operations Subcommittee hearing, Dr. Goldman spelled out the Agency's intention in more detail:

[EPA will] immediately discontinue processing applications for experimental use permits, product registrations, and petitions for tolerances for chemicals that are potentially affected by the Delaney Clause. It makes little sense to expend Agency resources to process applications for the same sorts of uses which we are in the process of revoking.... [T]he clear legal interpretation of the US Ninth Circuit Court's decision plainly applies to a number of other chemicals and their tolerances. Although there are a number of legal and policy issues which EPA has not yet settled, I have decided that we can quickly begin to make the policy choices and initiate actions on a number of existing tolerances. Accordingly, I expect that additional notices to revoke Section 409 tolerances will be proposed within a matter of months. (House Environment, Energy and Natural Resources Subcommittee, Government Operations Committee, October 29, 1993.)

In response to questions from subcommittee chairman Synar, Dr. Goldman then provided a list of carcinogens potentially subject to Delaney, indicating that under EPA's plan for these chemicals, the Agency "will establish priorities and schedules over the next year for revoking food additive regulations and raw food tolerances, as well as possibly cancelling registrations."

Responding elsewhere to industry criticism of EPA's intention to act on § 408 as well as § 409 tolerances in order to fully ensure compliance with the Delaney Clause, the Assistant Administrator has also stated that:

The EPA disagrees that it is mistaken to invoke the Delaney Clause for raw tolerances under all circumstances. We are aware that, in many cases, the farmer does not know ahead of time whether a given crop is destined for the raw or processed market. It would be misleading and disruptive for the EPA to grant raw tolerances in circumstances where later the crop is destined for the processed market and, therefore, would have violative residues. (Pesticide and Toxic Chemical News, November 10, 1993, at 20.)

This Administration's express commitment to Delaney implementation is refreshing since, in the past, at least for pesticides, the Delaney Clause has been honored in the breach. The Agency's consistent approach throughout the 1980s with respect to carcinogens in food was to ignore or invade that historic statute. This approach is no longer legally permissible. The United States Court of Appeals has held, in Les v. Reilly, that pesticides present in processed foods, either due to concentration during processing or post-harvest application, are subject to Delaney. The Agency's purported "de minimis" policy, allowing carcinogens based on the purported level of cancer risk, was rejected because "the language of the Delaney Clause, its history and purpose, all reflect that Congress intended the EPA to prohibit all additives that are carcinogens, regardless of the degree of risk involved." (Les v. Reilly)

Moreover, under the Agency's well-established policy, and because EPA is unable to determine which raw commodities will or

will not be processed, the presence of carcinogenic pesticides in raw commodities that are subject to processing is foreclosed as well.

Beginning to fulfill this commitment to Delaney compliance, EPA has now issued an updated list of those carcinogenic pesticides that have been identified as subject to the Delaney Clause (copy attached). This is an important first step. However, in order to obey the law and protect the public health, it is now incumbent upon the Agency to take all appropriate steps, in a timely fashion, to revoke those offending tolerances. It has been 18 months since this Administration first announced its intention to obey the law. It is now time to start actually doing so.

III. The Promise of the Delaney Clause Remains Unfulfilled

The essential premise of the Delaney Clause of the Food, Drug and Cosmetic Act is as simple as it is powerful: what we understand best about carcinogens is the limited extent of our knowledge. (See "No More Pesticides for Dinner," New York Times, March 9, 1993, copy attached.) Accordingly, the famous clause is grounded in a policy of prevention: prohibiting the addition of carcinogens in the food supply to prevent avoidable cancers in humans. This approach was deemed necessary by Congress, since the entire nation's population would otherwise be routinely exposed to carcinogens in their daily diet. That premise remains as valid today as it was in 1958.

Accordingly, the philosophy behind the Delaney Clause -- preventing unnecessary exposure to hazardous substances -- should be preserved -- either by implementation of the existing law or in any new legislation. Prevention is worth a pound of cure. We still do not know whether humans are more or less sensitive than laboratory animals to carcinogens and whether one carcinogen may increase the cancer-causing effects of another. We still do not know the cumulative impact of dozens of carcinogens permitted in the food supply and the environment. Our existing tolerance-setting system is entirely predicated on a chemical-by-chemical, crop-by-crop, risk-by-risk approach, grounded in myopia, "managing" cancer, rather than preventing it.

The reality of life is that we are exposed to a multiplicity of toxic substances. Calculating the combined risks of these exposures is problematic at best; some 300 pesticide active ingredients are used on food as well as an imperfectly examined large number of "inert" ingredients. For the most part, existing EPA pesticide tolerances for allowable pesticide residue levels do not even attempt to calculate the aggregate human health risks presented, nor do they address the cumulative and synergistic effects on multiple pathways of exposure.

This is the fundamental flaw in the nation's pesticide laws. And it is the fundamental flaw in the Administration's proposal which, while improving the current system, keeps its essential "management" approach intact. We, instead, should follow Rachel Carson's advice of three decades ago:

The ultimate answer is to use less toxic chemicals. This system of deliberately poisoning our food and then policing the result is too reminiscent of Lewis Carroll's 'white knight' who thought of a plan to dye one's whiskers green and always use so large a fan that they could not be seen.'

IV. The Need for Phase-Out

While many approaches to do so are feasible, the linchpin of any comprehensive reform legislation must be the accomplishment of the following three goals:

- ▲ Comprehensively deal with chronic health hazards from pesticides by phasing out those toxic substances identified as presenting known hazard to human health and the environment;
- ▲ Respond to the special risks pesticides pose to children as most recently recognized in the National Academy of Sciences report on that subject; and
- ▲ Substantially reduce overall pesticide use in American agriculture.

Absent such reforms, the Delaney Clause should be left intact and its terms complied with to the full extent of the law. Consider the following. Since the time the Delaney Clause was enacted:

- ▲ Conventional pesticide use in the United States has increased dramatically, from 511 million to more than one billion pounds. Total pesticide use, including wood preservatives, disinfectants and sulfur now exceeds two

billion pounds annually, eight pounds for every man, woman and child in the United States.

- ▲ EPA estimates that one out of every 10 public drinking water wells in the US contains at least one pesticide; their data indicate that nearly 10,000 community drinking water wells and over 440,000 domestic water wells contain pesticides. Seventy-four different pesticides have been found in groundwater which supplies drinking water for 32 states. Agriculture is also now the number one source of pollution of surface water; pesticides have found their way into countless lakes, rivers and waterways throughout the nation.
- ▲ According to the FDA, at least 38 percent of the food supply contains pesticide residues. This understates the actual amount because routine lab tests detect fewer than half of the pesticides applied to food. Many foods sampled by FDA had more than one pesticide residue; some had as many as twelve.
- ▲ The bugs are winning. At the time the Delaney Clause was enacted, 137 species of insects and mites had become resistant to chemical pesticides. Today, the number of resistant pests is almost 500 (as well as 100 species of plant pathogens and 48 species of weeds).

In 1972, Congress required that the chemical industry test their products and the government reassess their safety. For fifteen years, this requirement went largely ignored. Finally, in 1988, Congress established explicit timetables by which such

testing must be completed, to be concluded by 1997, and for pesticides to be "reregistered" based on the results. Yet, to date, only 27 of 600 active ingredients have been reregistered (and EPA may miss this deadline by a decade or more).

Nonetheless, in laboratory tests, 71 different pesticides allowed in food and the environment have now been found to cause cancer.

Mounting evidence suggests a strong correlation between pesticide exposure and the development of cancer in humans. A National Cancer Institute (NCI) study found that farmers exposed to herbicides had a six times greater risk than nonfarmers of contracting one type of cancer. Another study found a link between breast cancer in women and elevated levels of DDE, a metabolite of the pesticide DDT, in their fat tissue. Research also indicates that children in homes where household and garden pesticides are used are seven times as likely to develop childhood leukemia. There are still unexplained clusters of cancer among farmworker children at places such as McFarland and Earlimart, California.

Those of us born after World War II -- the "boomers" -- have been accurately called "the children of the chemical age." It always seemed something of a compliment. But in a disturbing new study, researchers have found that "baby boomers" born between 1948 and 1957 are far more likely to contract cancer than members of their grandparents' generation. These scientists found persistent increases in cancer that could not be accounted for by smoking, aging, or better diagnostic tests. The types of tumors

found to be increasing in the general population were also strikingly similar to those found in earlier studies of farmers who were exposed to a variety of carcinogens, such as fertilizers, pesticides and other solvents.

Authored by epidemiologist Devra Lee Davis, the study, published recently in the Journal of the American Medical Association, found that cancers unrelated to smoking -- that affect parts of the body other than the lungs, throat and mouth - - were occurring in white male "boomers" at triple the rate of their grandfathers. White women in the same age group had 30 percent more non-smoking related cancer than their grandmothers. (The study was conducted only of whites to avoid statistical problems having to do with diet.)

Given this record, the case is compelling to, once and for all, end business as usual. American agriculture must move in a new direction -- a direction that simply relies far less on toxic chemicals to produce our food. The first step in that journey must be the slow, but eventual, phase-out of "worst actor" pesticides, chemicals whose hazards have been well-known for up to 50 years. See White Paper: The Need for a Phase-Out of Carcinogenic Pesticides, Natural Resources Defense Council (copy attached).

V. Pesticide Reduction: The Pollution Prevention Solution

Current regulatory programs have been unable to reduce the hazards caused by pesticides. Ultimately, the most effective

method for protecting public health and the environment is to reduce the use of pesticides at their source. Numerous reports document the potential and importance of reducing overall use of pesticides.¹ According the National Academy of Science's Soil and Water Quality: An Agenda for Agriculture NAS report,

Source control to reduce the total mass of pesticides applied to cropping systems should be the fundamental approach to reducing pesticide losses from farming systems.²

Several European countries including Sweden, Denmark and the Netherlands have adopted national programs that incorporate the fundamental approach of pesticide use reduction. Concern about environmental pollution has prompted these countries to initiate programs aimed at reducing the use and emissions of, and dependence on, pesticides while maintaining viable levels of crop protection without decreasing crop yields.

Although not perfect, these programs are models for what is possible in the U.S. The Swedish program achieved a 50 percent reduction in the weight of active ingredient applied between 1986 and 1991 and an additional 50 percent cut is currently being

¹ National Research Council, Soil and Water Quality: An Agenda for Agriculture, Washington, D.C., 1993.

Office of Technology Assessment, Beneath the Bottom Line: Agricultural Approaches to Reduce Agrichemical Contamination of Groundwater, Washington D.C., 1991.

² Soil and Water Quality, p. 82.

implemented. The Danish program achieved a 25 percent reduction between 1986 and 1990.³

Numerous methods are available to reduce agriculture's use of and reliance on pesticides. The National Academy of Sciences in their report, Alternative Agriculture documented the potential for reducing pesticide use through the adoption of integrated pest management and other practices and systems for agricultural sustainability. Such practices can lower costs for farmers and pest managers and in many cases increase the quality, productivity and yields.⁴

According to a 1991 NRDC report, Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use, techniques are available to reduce the use of pesticides between 25 and 80 percent on nine different cropping systems throughout the U.S..⁵ Depending on the crop, methods such as integrated pest management and biological, cultural, mechanical and physical controls can be implemented without significantly effecting crop yields or production costs (Executive Summary attached).

Federal programs have failed to encourage and, in many cases, have impeded the adoption of pest management methods that reduce the use of pesticides. Farmers are interested in

³ World Wildlife Federation, Pesticide Reduction Programmes in Denmark, The Netherlands, and Sweden, November 1992, pp. 29-34.

⁴ Alternative Agriculture.

⁵ Curtis, Jennifer, et al., Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use, Natural Resources Defense Council, May 1991, p. iii.

implementing new approaches but poorly funded and uncoordinated federal programs have been of little assistance.

The public is looking to Congress for action. A comprehensive federal program that encourages the trend towards reduced use of pesticides is long overdue. Legislation is needed to mandate a program that includes, at a minimum, the following major components:

- (1) Measurable and enforceable pesticide reduction goals.
- (2) Regional, ecosystem-based and crop-specific pesticide reduction programs that broadly involve farmers and other experts in integrated pest management and sustainable agricultural systems.
- (3) Substantial resources directed towards technology transfer for pesticide reduction, including model demonstration farms and cost-share assistance.
- (4) Prioritization of existing pest management research and extension activities towards development of integrated pest management and sustainable agricultural systems.
- (4) Complete pesticide record-keeping and use reporting.
- (5) Establishment of pesticide reduction goals and programs for all federal agencies.
- (6) Creation of market incentives for farmers including through government procurement of certified-organically grown food.

(7) Development of nationwide initiative to reduce the use of nonagricultural pesticides.

VI. The Administration's Proposal: Only a Starting Point

Strange things are happening in the Great Lakes. Male birds are developing female sexual organs. Other waterfowl are suffering birth defects, behavioral changes and total reproductive failure. Among the suspected causes: exposure of bird eggs to the pesticide DDT. The suspected reason is that DDT is "estrogenic," mimicking the properties of estrogen in the human body. While DDT is off the market (but still in the environment) a number of other estrogenic pesticides, such as endosulfan, are still widely used. What we are doing to our waterfowl, we are also doing to ourselves.

In Earth in the Balance, Vice President Al Gore wrote this about agrichemicals:

Over the past fifty years, herbicides, pesticides, fungicides and thousands of other compounds have come streaming out of the laboratories and chemical plants faster than we can possibly keep track of them. All of them are supposed to improve our lives.... But too many have left a legacy of poison that we will be coming to terms with for many generations.

The Vice President had it right. Last fall, the Clinton Administration admirably chose to break the logjam over pesticides. But, unfortunately, their initial proposal, reflecting an interagency compromise on agricultural interests and public health, missed the mark. At best, it is a first step.

The proposal is opposed by every major environmental, consumer and labor organization in the country. Here's why.

Under current law, residues of dozens of cancer-causing pesticides are routinely allowed in raw foods, such as fruits and vegetables, through application of a notoriously weak, "cost-benefit" standard. On the other hand, as a result of a recent court decision, pesticides in processed foods are subject to the nation's most health-protective statute, the Delaney Clause, prohibiting any residue of a known carcinogen. The Clinton proposal would replace this admittedly schizophrenic scheme with a "negligible risk" standard to apply to all foods -- raw and processed.

As always, the devil is in the details. First, the Administration proposal does not specify precisely what constitutes such a negligible cancer risk -- or even agree to include a definition in the statute itself. Instead, identifying the "acceptable" number of cancers permitted from daily exposure to pesticides in the nation's food supply would be left to the discretion of both this and future Administrations. Given typical industry influence over government regulators and the open hostility of prior Administrations to pesticide regulation, this proposal offers little comfort.

Moreover, for at least the next decade, the Administration's new standard will apply only when it will not result in "disruption of agricultural production." This loophole is left vague and undefined. But historically, for thirty years or more,

virtually each time EPA has attempted to regulate a pesticide -- from DDT to DBCP to EDB to Alar -- efforts were stymied by overstated industry claims of just such predicted "disruptions."

The Administration's proposal also responds only with vague generalities to a recent National Academy of Sciences study concluding that existing pesticide laws do not adequately protect infants and children from their daily dose of these poisons. And it does not adequately address the cumulative impact of exposure to the multiple pesticides found in our foods, including the ability of one toxin to greatly increase the hazard of another, called synergism. Rather than simply assigning individual "acceptable" residue levels, on a chemical-by-chemical basis, for the 300+ pesticides used in food, any reform proposal should, instead, gradually eliminate the use of pesticides already known to pose the gravest threat to human health.

In addition, the Administration's proposal falls short of developing a nationwide program to reduce the use of and reliance on pesticides. While an important first step, the Administration's proposal is limited to authorizing establishment of reduced use pilot projects. Both farmers and the public deserve a comprehensive federal program that establishes measurable goals for pesticide reduction, provides substantial resources for technology transfer and cost-share assistance for farmers and requires federal agencies to take the lead in pesticide reduction efforts.

VII. Conclusion

Years ago, the Moss Committee of this body found American pesticide laws "to be an abysmal failure in need of a complete overhaul." That conclusion remains accurate. Serious reform is required, and will be accomplished only through leadership from the White House. Fortunately, time remains for the Clinton Administration to fulfill its campaign promise to achieve tough and meaningful environmental protection, including long over-due pesticide reform. Otherwise, an historic opportunity -- as well as the critical goal of reducing human exposure to these most toxic of chemicals -- may be lost.

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STATISTICS FOR POTENTIALLY CARCINOGENIC PESTICIDES

PESTICIDES					"DELANEY CHEMICALS"				
A CANCER CLASS	B NUMBER REVIEWED	C NOW REGISTERED	D WITH TOLERANCES	E WITH DIETARY RSKS > 10 ⁻⁶	F TOTAL 408 & 409 TOLERANCES	G WITH 408s # # chems 409s	H 408s NEEDED	I AFFECTED CROPS	
GROUP A:	3	2	0	0	0	0	0	0	
GROUP B1:	3	2	0	0	0	0	0	0	
GROUP B2:	52	25	24	21	365	4	26	31	
GROUP C:	26	22	21	16	590	7	18	19	
GROUP C MONO:	44	40	33	NA	591	9	18	34	
OTHER	3	3	3	NA	92	2	3	7	
TOTALS:	131	95	81	37	1628	22	66	91	

NOTES:

"Delaney Chemicals"—pesticides which are likely subject to the Delaney clause because of concentrations in processed food or feed forms.

The following notes refer to Columns A through H of the table.

- See explanation of EPA's cancer classification system below.
- Reviewed by CFP and/or others (e.g., MNC, CAG, and CHAVE).
- Members now registered are approximately 409, voluntary cancellations due to registration may not be reflected.
- Includes Column A chemicals which have 409 and/or 409 tolerances, even if they are cancelled, if the tolerance revocations are not yet final.
- Members are approximately theoretical levels, based, in many cases, on theoretical maximum residues and include both published and pending tolerances. In cases such as the BDCs, if their cumulative theoretical risk exceeds 10⁻⁶, all are carried.
- These numbers represent all tolerances for "Delaney chemicals", whether Delaney would force their revocation or not. This mostly serves to give an idea of the number of tolerances that could be affected if we are decided to eliminate the pesticides subject to the Delaney clause.
- 409 needed (Column H) indicates that we have a study which shows concentrations in a processed food or feed. There is some indication of chemicals in these two columns since a chemical which already has a 409 may be found to need one for another processed food or feed; 14 chemicals appear on both lists. The total number of pesticides which appear to be subject to Delaney is 40.
- These numbers represent the number of crops that would be affected by revocation or denial of all 409s.

Justification of these positions is based on a weight-of-evidence determination made generally within EPA and is in accordance with EPA's Cancer Assessment Method. The classifications are as follows:

Group A: Human Carcinogen (sufficient evidence of carcinogenicity from human epidemiologic studies);

Group B:

- B1: Probable Human Carcinogen
- B2: Limited evidence of carcinogenicity from human epidemiologic studies
- B2: Sufficient evidence of carcinogenicity from animal studies;

Group C:

Probable Human Carcinogen

- there is limited evidence of carcinogenicity in animals in the absence of human data, including malignant tumor response in a single well-conducted experiment not meeting conditions for sufficient evidence;
- tumor responses of marginal statistical significance in studies having inadequate design or reporting;
- benign tumors where short-term mutagenicity tests are negative and responses of marginal statistical significance in a tissue with high background rate;

Group D: Not Classifiable as to Human Carcinogenicity (either adequate evidence of carcinogenicity or absence of data); and

Group E: Evidence of Non-Carcinogenicity for Humans (no evidence of carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animal studies)

IARC - International Agency for Research on Carcinogenicity

CAG - Cancer Assessment Group

CRABE - Carcinogenicity Risk Assessment Verification Endeavor

TOTAL NUMBER OF TOLERANCES ON THE BOOKS		
400s	400s	
8,000	200 Food	200 Food



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 31 1994

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APR 4 1994

NRDC-SF

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Updated Lists Of Pesticides And Uses That
May Be Affected By The Delaney Clause

TO: Addressees

Attached for your information is a Note to Correspondents and Federal Register Notice that discuss the revised lists of pesticides and uses that EPA believes may be affected by the Delaney clause. The lists are based upon EPA's interpretation of the court decision issued by the U.S. Circuit Court of Appeals for the Ninth Circuit regarding the Delaney clause of the Federal Food, Drug and Cosmetic Act (FFDCA).

If you need additional information, or have any questions, please contact Scott Schwenk of my staff at 305-5077.

A handwritten signature in cursive script, reading "Margie Fehrenbach".

Margie Fehrenbach, Chief
Communications Branch
Field Operations Division

Attachments



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Note to Correspondents

WEDNESDAY, MARCH 30, 1994

EPA is issuing updated lists of registered pesticides and their uses that the Agency believes may be affected by the Ninth Circuit Court of Appeals decision (*Les vs Reilly*, July 8, 1992) concerning the Delaney clause. The initial lists, issued on Feb. 2, 1993, contained 32 pesticides used on over 80 different crops or commodities. The new list contains 34 pesticides and 100 different crop or commodity combinations. The pesticides in both List I and II, below, have been identified as possible or probable human carcinogens based on testing with laboratory animals.

As a minimum, EPA is required to revoke processed food tolerances for those pesticides found to be unlawful under the Delaney clause. In the year since the original list was issued, EPA has taken action to revoke tolerances for a number of pesticides and the Agency expects to initiate more revocation actions shortly.

"According to the data we have available, the Agency does not believe that the pesticides in the following lists pose a significant risk to public health," said Carol Browner, EPA Administrator. "Nevertheless, we are legally required to implement the Court's reading of the Delaney Clause. We do believe that the nation's pesticide laws need to be reformed. We are working with Congress to develop legislation that will protect our food supply by applying a single, strict, health-based standard to all pesticides, all foods, and all risks to human health. Our legislation would also reduce pesticide use overall."

R-77

(more)

-2-

The Delaney clause of the Federal Food, Drug, and Cosmetic Act provides that no chemical may be approved for use in processed food if it is found to induce cancer in man or animals. In 1988 EPA adopted a policy interpreting the Delaney clause as subject to an exception for carcinogenic pesticides which pose only a negligible risk. The Natural Resources Defense Council and others challenged EPA in court, seeking a "zero risk" interpretation of the Delaney clause. The court concluded that the Delaney clause is not subject to the Agency's negligible risk interpretation. The court's decision applies to all cancer-causing pesticides used directly on processed food or which concentrate during processing.

Because EPA continues to receive and evaluate carcinogenicity data as well as data on residues in processed food, the number of pesticides and uses may change.

For more information, contact Al Heier at 202-260-4374.

R-77

John Kasper, Director
Press Services Division

PESTICIDE USES POTENTIALLY AFFECTED BY REVOCATION OF ALL 409 AND
CORRESPONDING 408 TOLERANCES

The release of these lists does not affect the regulatory status of the pesticides or tolerances identified. The pesticides and tolerances which have been added since Feb. 2, 1993, are underlined. Those which have been deleted are identified in the paragraph following the lists.

LIST I

The first list contains pesticides that have established section 409 tolerances.

PESTICIDES	RAW CROP (408s)	PROCESSED FOOD/FEED TOLERANCE (409s)
Acephate	Cotton Soybeans	Seed hulls, meal (186.100) Meal (186.100) Food handling establishments (185.100)
Benomyl	Apples Citrus Grapes Rice Tomatoes	Pomace (186.350) Pulp (186.350) Pomace (186.350) Raisins (185.350) Raisin waste (186.350) Hulls (186.350) Puree or Catsup (185.350)
Captan	Grapes	Raisins (185.500)
Dichlorvos (DDVP)	N. applicable	Packaged nonperishable food (185.1900)
Dicofol	N. applicable	Dried tea (185.410)
<u>Diﬂubenzuron (Gre- tabolite p-chlor- oaniline (PCA)</u>	<u>Soybeans</u>	<u>Hulls (185.2000)</u> <u>Soapstock</u>
Dimethipin	Cotton	Seed hulls (186.2050)
Dimethoate	Citrus	Pulp (186.2100)
Ethylene oxide	Whole Spices	Ground spices (185.2850)
Mancozeb	Barley Grapes Oats Rye	Bran (185.6300) Flour (185.6300) Milled Fractions (186.6300) Raisins (185.6300) Bran (186.6300) Flour (186.6300) Milled fractions (185.6300) Flour (185.6300)

	Rye	Bran (185.6300) Milled fractions (186.6300)
	Wheat	Bran (185.6300) Flour (185.6300) Milled fractions (186.6300)
Norflurazon	Citrus	Pulp, molasses (186.4450)
Oxyfluorfen	Cotton	Cottonseed oil (185.4600)
	Peppermint	Oil (185.4600)
	Spearmint	Oil (185.4600)
	Soybean	Oil (185.4600)
Phosmet	Cotton	Cottonseed Oil (185.3950)
Propargite	Apples	Pomace (185.5000)
	Citrus	Pulp (186.5000)
	Figs	Dried figs (185.5000)
	Grapes	Raisins (185.5000)
		Dried pomace (185.5000)
	Tea	Dried tea (185.5000)
<u>Propylene Oxide</u>	<u>N. Applicable</u>	<u>Cocoa (185.5150)</u> <u>Glace fruit (185.5150)</u> <u>Edible gums (185.5150)</u> <u>Processed nutmeat except</u> <u>peanuts (185.5150)</u> <u>Prunes (185.5150)</u> <u>Processed Spices (185.5150)</u> <u>Starch (185.5150)</u>
Simazine	Sugarcane	Molasses, syrup (185.5350) (186.5350) Potable water (185.5350)
<u>Tetrachlorvinphos</u>	<u>N. Applicable</u>	<u>Feed items (186.950)</u>
Thiophanate-methyl	Apples	Pomace (186.5700)
Triadimefon	Apples	Pomace (186.800)
	Barley	Milled fractions (185.800)
	Grapes	Pomace (186.800)
		Raisin wastes (186.800)
	Wheat	Milled fractions (185.800)
Trifluralin	Peppermint	Peppermint oil (185.5900)
	Spearmint	Spearmint oil (185.5900)

The following have been deleted since the Feb. 2, 1993, List I was issued: Captan raw tolerance for corn and food additive tolerance for detreated seed; Methomyl, Norflurazon, & Propargite raw tolerance for hops and food additive tolerance for dried hops.

LIST II

The following list of pesticides do not have established section 409 food additive tolerances, but based upon data indicating concentration during processing, they would require food additive tolerances under EPA's current policy. Pesticides and crops which appear on this list and List I are noted with "+".

PESTICIDE	RAW CROP (408s)	PROCESSED FOOD/FEED TOLERANCE
+Acephate	+Soybeans	Hulls
Alachlor	Peanuts Soybeans Sunflower seed	Meal Hulls, Meal Meal
Asulam	Sugarcane	Bagasse, Molasses
Atrazine	Sugarcane	Bagasse, Molasses
+Benomyl	+Rice <u>Soybeans</u>	Bran <u>Hulls</u>
+Captan	Apples +Grapes Plums Tomatoes	Dry pomace Raisin wastes Juice Dry Pomace Prunes, Dry Pomace
Chloroethalonil	Potatoes Soybeans	Wet peel Hulls
+Dichlorvos (DDVP)	N. Applicable	Food handling establishments
+Dicofol	Apples Citrus Grapes <u>Plums</u>	Dry pomace Oil Dry pomace Raisins Raisin wastes <u>Prunes</u>
+Dimethoate	Apples +Citrus	Juice Oil
Hexazinone	<u>Alfalfa</u> <u>Pineapple</u> Sugarcane	<u>Meal</u> <u>Bran, Molasses</u> Bagasse, Molasses
Lindane	Tomatoes	Dry pomace

Linuron	Potatoes	Dry & wet Peel, Chips, Dried Granules
	<u>Soybeans</u>	<u>Meal</u>
+Mancozeb	Apples	Dry pomace
	+Grapes	Raisin waste
	Sugar beets	Pulp
	+Wheat	Middlings
Maneb	Apples	Dry pomace
	Grapes	Raisin waste
	Sugar beets	Pulp
Methidathion	Citrus	Oil
Metiram	Apples	Dry pomace
	Sugar beets	Pulp
Metolachlor	Peanuts	Meal
Methomyl	Wheat	Bran
+ <u>Norflurazon</u>	+ <u>Citrus</u>	<u>Oil</u>
	<u>Grapes</u>	<u>Raisin waste</u>
+Oxyfluorfen	Apples	Dry pomace
PCNB	Potatoes	Wet & Dry Peel
	Tomatoes	Dry pomace
Permethrin	Tomatoes	Dry pomace
+Phosmet	Citrus	Oil
+Propargite	+Citrus	Oil
	+Grapes	Raisin wastes
	Plums	Prunes
+Simazine	+Sugarcane	Bagasse
+Triadimefon	Pineapple	Bran
+ <u>Trifluralin</u>	<u>Potatoes</u>	<u>Processed potato waste</u>

The following have been deleted since the Feb. 2, 1993 List II was issued. Alachlor raw tolerance on sorghum and food additive tolerance on sorghum bran, flour and germ. Dicamba raw tolerance on barley, millet, oats, and wheat and food additive tolerance on barley hulls, bran and pearl barley; millet hulls and meal; oat hulls and rolled oats; and wheat bran, shorts and middlings. Dicofof food additive tolerance for dried hops.

ENVIRONMENTAL PROTECTION AGENCY**[OPP-00374; FRL 4758-7]****Updated List of Pesticides and Uses Potentially Affected by the Delaney Clause of the Federal Food, Drug and Cosmetic Act****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Publication of Updated List of Pesticides.

SUMMARY: This Notice publishes an updated list of pesticides potentially affected by the Delaney clause in section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA).

ADDRESSES: A copy of the list is included in the public docket at Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

FOR FURTHER INFORMATION CONTACT: by mail: Deborah J. Hartman, Policy and Special Projects Staff, Office of Pesticide Programs, (7501C), Environmental Protection Agency, 401 M St., SW., Washington, DC, 20460. Office location and telephone number: Rm. 1113J, Crystal Mall #2; 1921 Jefferson Davis Highway, Arlington, VA., Telephone 703-305-7102.

SUPPLEMENTARY INFORMATION: EPA regulates pesticide residues in foods under the Federal Food, Drug, and Cosmetic Act (FFDCA). The FFDCA gives EPA the authority to set legally enforceable limits, or tolerances, for pesticide residues in food. EPA sets tolerances for pesticide residues remaining in raw foods under section 408 of the FFDCA. Under section 409 of FFDCA, EPA sets food additive tolerances for pesticide residues that concentrate in processed foods above raw food tolerances, or are the result of pesticide application during or after food processing.

To establish a tolerance or an exemption from a tolerance for pesticide residues on raw agricultural commodities under section 408 of the FFDCA, EPA must make a finding that the promulgation of the rule would "protect the public health." In reaching this determination, the Agency is directed to consider, among other relevant factors: (1) The necessity for the production of an adequate, wholesome and economical food supply; (2) other ways in which the consumer may be affected by the pesticide; and (3) the usefulness of the pesticide for which a tolerance is sought. Thus, section 408 of the FFDCA requires the Agency to balance risks against benefits in determining whether to establish tolerances.

The establishment of a food additive regulation in a processed food under section 409 requires a finding that use of the pesticide will be "safe." FFDCA section 409 also contains the Delaney clause, which specifically provides that, with limited exceptions, no additive may be approved if it has been found to induce cancer in man or animals. In 1988 EPA adopted an interpretation of the Delaney clause that allowed an exception for carcinogenic pesticides that pose only a negligible risk. In July 1992, the Ninth Circuit Court of Appeals overturned EPA's interpretation of the Delaney clause, holding that the Delaney

clause bars tolerances (maximum allowable levels of residues in food) for carcinogenic pesticides in processed food without regard to the degree of risk. See *Les v. Reilly*, 968 F.2d 985 (9th Cir.1992), cert. denied, 113 S. Ct. 1361 (1993).

A. February 1993 List of Potentially Affected Pesticide and Uses

In February 1993, the Agency released a list of 32 pesticides, representing over 80 different chemical/crop combinations that appeared to be potentially affected by the court's decision. EPA included pesticides on the list if they had been classified under the Agency's cancer classification scheme as probable (Group B) or possible (Group C) carcinogens and if section 409 tolerances have been established or would be required under current EPA policy because residues of the pesticide concentrate in processed food. The original list was issued in two parts. List I included those pesticides that had section 409 food/feed additive tolerances. List II included pesticides which did not have established section 409 food additive tolerances, but based upon data indicating concentration in processing would require such tolerances.

B. Process Followed to Update the List

EPA has updated the February 1993 lists by following the same process used to create the initial list. The Agency reviewed current data on the carcinogenicity of pesticides, and data on how pesticide residues concentrate when foods are processed. Such data are received throughout the process of evaluating whether a pesticide should be reregistered.

EPA has reviewed all pesticides classified as probable or possible human carcinogens in the past year and reviewed studies on how pesticide residues concentrate. In the case of pesticides having existing section 409 tolerances, the new pesticides, together with their uses, have been added to List I. Pesticides for which studies indicate concentration in processed food, therefore requiring section 409 tolerances, were added to List II. EPA has also added to List II pesticides used for direct treatment of processed food, food handling equipment, and other uses which are likely to result in residues in the processed food.

In the year since the original list was issued, EPA has taken action to revoke section 409 tolerances for a number of pesticides. EPA has deleted pesticides from List I if the food additive tolerance has been revoked. Pesticides/uses have been removed from List II if more recent data has shown that there is no concentration of residues during processing associated with the uses in question. Pesticides used on dried hops have also been deleted from the list because EPA has changed the regulatory status of dried hops. Dried hops had been regulated as a processed food, but now will be considered a raw agricultural commodity, for which tolerances are established under section 408 of FFDCA. (See "Status of Dried Hops under the Federal Food, Drug, and Cosmetic Act," PR notice 93-12, Dec. 23, 1993.)

Thirty-four pesticides are included on the updated list. The lists contain 100 chemical/crop or site combinations. (Fourteen pesticides and 10 pesticide/crop combinations appear on both lists.)

C. The Updated List of Pesticides and Uses Potentially Affected By the Delaney Clause

The following List I includes 20 pesticides that have established section 409 food/feed additive tolerances. Forty-eight pesticide/commodity combinations are included on List I. Notes and symbols used in List I and II are explained at the end of List II.

List I.—Pesticides Classified As Group B or C Carcinogens That Have Established Section 409 Food Additive Tolerances¹

Pesticide	Raw crop	Processed food/feed	Notes	CFR Cite
Acophate	Cotton	Seed: hulls, meal		185.100
	Soybeans	Meal		185.100
	Not applicable@	Food handling establishments		185.100
•Benomyl	Apples	Pomace		185.350
	Citrus	Pulp		185.350
	Grapes	Pomace	A	185.350
		Raisins		185.350
		Raisin waste		185.350
	Rice	Hulls		185.350
	Tomatoes	Puree or catsup	A	185.350
Captan	Grapes	Raisins		185.800
•Dichlorvos (DDVP)	Not applicable@	Pkgd nonperish. food	D, E	185.1900
Dicofol	Not applicable@	Dried tea	F	185.410
Dilubenzuron (metabolite) ² p-chloroaniline (PCA)	Soybeans ²	Hulls, Soapstock ²	*	185.2000
Dimethipin	Cotton	Seed hulls		185.2050
Dimethoate	Citrus	Pulp		185.2100
Ethylene oxide	Whole spices	Ground spices		185.2850
•Mancozeb	Barley	Bran		185.6300
		Flour		185.6300
		Milled fractions		185.6300
	Grapes	Raisins	A	185.6300
	Oats	Bran		185.6300
		Flour		185.6300
		Milled fractions		185.6300
	Rye	Flour		185.6300
		Bran		185.6300
		Milled fractions		185.6300
	Wheat	Bran	A	185.6300
		Flour	A	185.6300
		Milled fractions		185.6300
Norfurazon	Citrus	Pulp, molasses		185.4450
Oxyfluorfen	Cotton	Cottonseed Oil		185.4800
	Peppermint	Oil		185.4800
	Spearmint	Oil		185.4800
	Soybean	Oil		185.4800
•Phosmet	Cotton	Cottonseed oil	A	185.3850
Propargite	Apples	Pomace		185.5000
	Citrus	Pulp		185.5000
	Figs	Dried figs		185.5000
	Grapes	Raisins, Dried pomace		185.5000
	Tea	Dried tea		185.5000
Propylene oxide ²	Not applicable@	Cocoa ²	B	185.5150
		Glace fruit ²	B	185.5150

Pesticide	Raw crop	Processed food/feed	Notes	CFR Cite
		Edible gums ²	B	185.51
		Processed nutmeat (except peanuts) ²	B	185.515
		Prunes ²	B	185.5150
		Processed spices ²	B	185.5150
		Starch ²	B	185.5150
Simazine	Sugarcane	Molasses, Syrup		185.5350
	Not applicable@	Potable water		185.5350
Tetrachlorvinphos ²	Not applicable@	Feed items ²	B	186.950
Thiophanate-methyl	Apples	Pomace		186.5700
Triadimenol	Apples	Pomace		186.800
	Barley	Milled fractions		185.800
	Grapes	Pomace		186.800
		Raisin waste		186.800
	Wheat	Milled fractions		185.800
+Trifluralin	Peppermint	Peppermint Oil	A	185.5900
	Spearmint	Spearmint Oil	A	185.5900

¹Several 409s that have been proposed for cancellation are still included since revocations are not yet final.

²Use of this pesticide on this commodity has been added to the list.

The following List II shows pesticides that do not have established section 409 food additive tolerances, but based upon data indicating that residues present on a raw agricultural commodity concentrate during processing, they would require food additive tolerances under EPA's current policy. Fifty-two pesticide/commodity combinations are included on List II. Pesticides and crops which appear on both this list and List I are noted by "+."

List II.—Pesticides That Do Not Have Established Section 409 Food Additive Tolerances¹

Pesticide	Raw crop	Processed food/feed	Notes
+Acephate	+Soybeans	Hulls	
Alechlor	Peanuts	Meal	
	Soybeans	Hulls, meal	
	Sunflower seed	Meal	
Azulen	Sugarcane	Bagasse, molasses	
Atrazine	Sugarcane	Bagasse, molasses	
+Benomyl	+Rice	Straw	
	Soybeans ²	Hulls ²	C
+Captan	Apples	Dry pomace	
	+Grapes	Raisin waste, juice, dry pomace	
	Plums	Prunes	
	Tomatoes	Dry pomace	
Chlorothalonil	Potatoes	Wet peel	
	Soybeans	Hulls	
+Dichlorvos (DDVP)	Not applicable@	Food handling establishments	D
+Dioctol	Apples	Dry pomace	
	Citrus	Oil	
	Grapes	Dry pomace, raisins, raisin waste	
	Plums ²	Prunes ²	C

Pesticide	Raw crop	Processed food/feed	Notes
•Dimethoate	Apples •Citrus	Juice Oil	
Hexazinone	Alfalfa ² Pineapple ² Sugarcane	Meal ² Bran, molasses ² Bagasse, molasses	C C
Lindane	Tomatoes	Dry pomace	
Linuron	Potatoes Soybeans ²	Dry & wet peel, chips, dried granules Meal ²	C
••Mancozeb	Apples •Grapes Sugar beets •Wheat	Dry pomace Raisin waste Pulp Middlings	
Maneb	Apples Grapes Sugar beets	Dry pomace Raisin waste Pulp	
Methidathion	Citrus	Oil	
Metiram	Apples Sugar beets	Dry pomace Dry pomace	
Metolachlor	Peanuts	Meal	
Methomyl	Wheat	Bran	
•Norflurazon ²	•Citrus ² Grapes ²	Oil ² Raisin waste ²	C C
•Oxyfluorfen PCNB	Apples Potatoes Tomatoes	Dry pomace Wet & dry peel Dry pomace	
Permethrin ••Phosmet	Tomatoes ² Citrus	Dry pomace Oil	
•Propargite	•Citrus •Grapes Plums	Oil Raisin waste Prunes	
•Simazine	•Sugarcane	Bagasse	
•Triadimefon	Pineapple	Bran	
••Trifluralin ²	Potatoes ²	Processed potato waste ²	C

¹As noted in the table, some pesticides are listed because their registered uses include contact with food processing, handling, or storage areas, or equipment.

²Use of this pesticide on this commodity has been added to the list.

Notes Used in Lists I and II.

@ For some of the pesticides listed, a tolerance is established for residues on the processed food or feed items, and there is no corresponding tolerance on a raw agricultural commodity. In these instances, the entry in the "raw crop" column is "Not Applicable."

• A pesticide which EPA has concluded "induces cancer" within the meaning of the Delaney clause. The Delaney clause specifically provides that, with limited exceptions, no food additive may be approved if it is found to induce cancer in man or animals. For an explanation of the "induce cancer" standard, see the final rule revoking the food additive regulations for benomyl, mancozeb, phosmet, and trifluralin (58 FR 37863, July 14, 1993.)

A. EPA issued a final rule revoking the food additive tolerances for benomyl (on raisins and processed tomato products), mancozeb (on raisins and bran of wheat),

trifluralin (on spearmint and peppermint oil), and phosmet (on cottonseed oil). (See 58 FR 37862, July 14, 1993). EPA revoked the tolerances because they were inconsistent with the Delaney clause. However, the Agency received several objections and petitions to stay the effective date of the revocations. On September 16, 1993, EPA issued an order staying the effective date during the time needed for EPA to review and respond to the stay requests.

B. Added because EPA has evaluated the pesticide for potential carcinogenicity and classified it as a probable or possible human carcinogen.

C. Added because EPA has determined under its current concentration policy that the residues of the pesticide concentrate in the processed food form.

D. EPA expects to issue a Notice of Intent to Cancel registrations of certain DDVP uses in food handling establishments which would result in unlawful residues in processed food.

E. The Agency published a notice to revoke the use of dichlorvos (DDVP) in Bagged/Packaged nonperishable processed food. The revocation was published on November 10, 1993, with an effective date of March 10, 1994. EPA received a request to stay the effective date. On March 10, 1994, EPA issued an order staying the effective date during the time needed for EPA to review and respond to a petition objecting to the revocation.

F. Dicofol: Use on dried tea, revocation published 59 FR 10993, March 9, 1994; effective date May 9, 1994.

* Indicates that the pesticide has been included because of a potential carcinogenic metabolite PCA. Diflubenuron has not been classified by EPA as a potential human carcinogen.

** The registration for permethrin is limited to use on tomatoes to be sold fresh in the marketplace, and is not registered for uses on processed food/feed commodities.

The following tables show the pesticides and uses which have been either added to or deleted from the list of pesticides potentially affected by the Delaney clause.

1. *Additions to the Lists—*a. List I.** The following pesticides/use combinations have been added to List I (Pesticides classified as Group B or C carcinogens that have established section 409 food additive tolerances.)

Pesticide	Raw Crop	Processed Food/Feed
Diflubenuron (metabolite PCA)	Soybeans	Hulls, Scapestock
Propylene oxide		Cocoa Glaze fruit Edible gums Dried nutmeat (except peanuts) Prunes Spices Starch
Tetrachlorvinphos		Feed items

b. *List II.* The following pesticide/use combinations have been added to List II (Pesticides classified as B or C carcinogens that do not have established section 409 food additive tolerances, but based upon data indicating concentration during processing, would require food additive tolerances under EPA's current policy.)

Pesticide	Raw Crop	Processed Food/Feed
Benomyl	Soybeans	Hulls
Dicofol	Plums	Prunes
Hexachlorocyclopentadiene	Alfalfa	Meal

Pesticide	Raw Crop	Processed Food/Feed
	Pineapple	Bran, molasses
Linuron	Soybeans	Meal
Nonflurazon	Citrus	Oil
	Grapes	Raisin waste
Tinfluralin	Potatoes	Processed potato waste

2. *Deletions from the List— a. List I.* The following pesticide/use combinations have been deleted from List I, for reasons noted at the end of this section.

Pesticide	Raw Crop	Processed Food/Feed	Notes	CFR Cite
Captan	Corn	Seed (detreated)	A	185.500
Ethylene oxide	Copra, Black walnut meats		B	185.2850
Methomyl	Hops	Dried hops	C	185.4100
Nonflurazon	Hops	Dried hops	C	185.4450
Propargite	Hops	Dried hops	C	185.5000

Notes:

A. Deleted because EPA revoked the food additive regulation. EPA published the following final revocations:

Captan: Use on detreated corn seed, revocation published 58 FR 41430, effective date August 4, 1993.

Propylene Oxide: An exemption from the requirement to obtain a section 408 tolerance for all raw agricultural commodities has been revoked, effective 10/21/93.

B. The use of ethylene oxide on copra and black walnut meats has been deleted because it was incorrectly listed on the February 1993 list. The section 409 tolerance for ethylene oxide is for its use as a fumigant on whole spices—there is no tolerance established for use on copra and black walnuts.

C. Uses noted were deleted due to a change in EPA guidelines with respect to the classification of dried hops. Consistent with the directive contained in Public Law 103-124, the appropriations act including EPA funding for FY94, on December 23, 1993, the Agency issued a notice to registrants informing them that dried hops are reclassified as a raw agricultural commodity (RAC). This eliminates the requirement for a food additive regulation for pesticides used on hops. As time and resources permit, EPA will revoke existing section 409 tolerances for dried hops, and issue section 408 tolerances in accordance with the reclassification of hops as a RAC. EPA intends to apply the reclassification of dried hops in all future regulatory decisions involving hops.

b. *List II.* The following pesticide/use combinations have been deleted from List II, for reasons noted on the list.

Pesticide	Raw Crop	Processed Food/Feed	Notes
Alachlor	Sorghum	Bran, Flour, Germ	A
Dicamba	Barley	Hulls, bran, pearl	B
	Millet	barley	
	Oats	hulls, meal	
	Wheat	Hulls, rolled oats, bran, shorts, middling	
Disulfid		Dried hops	C

Notes:

A. Deleted because sorghum bran, germ and flour are not food/feed items. Therefore, no food additive tolerance is required. This pesticide/use combination was

incorrectly included on the February 1993 list of pesticides and uses potentially affected by the Delaney clause.

B. Deleted because studies of the pesticide's residue in processed food indicate that the residue does not concentrate in the commodities noted.

C. Deleted due to change in EPA guidelines with respect to the classification of dried hops. (See note C above explaining deletions from List I.)

E. Today's List Does Not Constitute a Final Determination of Pesticides With Uses Prohibited By the Delaney Clause

For several reasons, the list of pesticide uses affected by the court's interpretation of the Delaney clause may be smaller than the lists made available by this notice. First, EPA has not made a final determination whether all of these pesticides "induce cancer" within the meaning of the Delaney clause. Second, many of the pesticide uses involve animal feeds, and EPA has not evaluated whether those uses qualify for the limited exception to the Delaney clause for animal feeds (the so-called "DES proviso"). Third, EPA has issued requests for comment on several policy issues, the resolution of which will affect precisely what pesticides and uses are affected. Fourth, in accordance with the requirements of the FFDCA, EPA's process for revoking pesticide tolerances provides the opportunity for public notice and comment on any proposed revocations. By the same reasoning, however, the lists do not reflect all pesticide uses that may be affected. EPA, through its registration and reregistration programs, continually receives new data. New studies may identify additional pesticides or uses that are subject to the Delaney clause. EPA intends to update and reissue both List I and II periodically.

List of Subjects

Environmental protection.

Dated: 21 March 1994

Lynn R. Goldman

Lynn R. Goldman,
Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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**WHITE PAPER:
THE NEED FOR A PHASE-OUT
OF CARCINOGENIC PESTICIDE RESIDUES**

Natural Resources Defense Council

DRAFT: September 10, 1993

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WHITE PAPER:
THE NEED FOR A PHASE-OUT
OF CARCINOGENIC PESTICIDE RESIDUES

Introduction and Summary

There is now an opportunity for a major shift in the way the nation's agricultural system does business--to help farmers and consumers. As a nation, we must put the "pollution prevention" and "pesticide use reduction" concepts embraced by the Clinton Administration to work, by taking immediate and direct steps to shift away from the use of older, more dangerous, cancer-causing pesticides, and towards alternative pest management approaches that pose less risk. One central driving force in this shift should be the adoption of the principle that we should not be intentionally adding carcinogens to our food supply. We should be phasing out the use of carcinogens and phasing in the use of alternatives.

The technical and scientific reasons for a phase-out/phase-in are many. There are substantial uncertainties inherent in quantitative risk assessment due to data gaps and methodological problems that necessitate a phase out of carcinogenic pesticides:

- o As the National Academy of Sciences' recent report on pesticides in children's food emphasized, risk assessments used to determine, for example, whether a pesticide supposedly poses a "one in a million risk," do not address cumulative risk posed by that pesticide from all sources of exposure (such as air, drinking water, food, etc.), yet such multiple sources of exposure should be considered.
- o The Academy also highlighted that risk assessments fail to consider the risks posed by the interactions of multiple cancer-causing or otherwise toxic pesticides on the same food or in the complete diet. Since a single meal may contain ten or more pesticide residues, this is a critical failure.
- o Even if a pesticide were said to pose a "one in a million" risk in food, there generally are far greater risks posed by the pesticide to farmers, farm workers, and the chemical workers who make the pesticide.
- o It is important to consider that some subpopulations, including infants, children, and poor people (especially poor children) are likely at especially high risk, but accurate prediction of these risks is severely hampered by serious gaps in exposure, toxicity, sensitivity, and interactive effects data.

Ultimately, as in the case of CFCs, methyl bromide, and other ozone depleters, there should be a phase out of food

tolerances for carcinogenic pesticides over the next five to seven years. Those carcinogenic food use pesticides whose tolerances can most readily be phased out should be revoked first, based upon a schedule established by EPA considering the availability of alternatives. Upon a finding by EPA that there are safer alternative methods of pest management that would not lead to a carcinogenic food residue, EPA should be required to revoke the tolerance for that carcinogenic pesticide residue. No new tolerances for pesticides that are carcinogens should be issued.

Tolerances for pesticides now categorized as A, B, and "possible" human carcinogens whose risks EPA has determined are quantifiable ("Cq") should be phased out no later than 7 years from the date of enactment. Any tolerance for a pesticide which EPA has already determined is a possible human carcinogen but whose risks are not quantifiable ("unquantifiable C") should be covered by the phaseout on the same date as a Cq pesticide unless the registrant demonstrated to EPA's satisfaction that its chemical is probably not a carcinogen. Food tolerances for existing pesticides determined to be A, B, or C carcinogens for the first time after the date of enactment should be phased out within 7 years from such determination. These phase outs would result in the revocation of the carcinogenic pesticide's tolerance by operation of law without further EPA action at the end of the "sunset" period. The law should provide a clear process for one-stop EPA determinations of the category of the pesticide. Pending the ultimate phase-out, progress must be made towards implementing alternatives and eliminating the carcinogenic pesticide's tolerance.

In tandem with this phase-out of carcinogenic pesticide tolerances, EPA and USDA should be required to adopt an aggressive national program of research, development, and local demonstration to identify and assure the availability of alternatives to the pesticides subject to the tolerance phase out.

Why a Phase-Out is Needed.

Quantitative risk assessment remains part art, part science. There are numerous areas of uncertainty involved in developing an estimate of the risk potentially posed by a pesticide residue or by any other environmental pollutant. Uncertainties derive from a broad array of problems, including gaps or uncertainties in toxicological data, our failure to understand the differences between the effects of a chemical on laboratory animals versus humans, problems in determining what subpopulations such as children are at special risk, difficulties in translating from high dose to low dose exposures, the lack of hard data on actual

exposure to the chemical from multiple sources, and many other problems.

When these uncertainties arise, the risk assessor seeks to make reasonable assumptions about the missing data, and plugs those values, and sometimes "safety factors" intended to try to compensate for possible underestimation of risks, in reaching the final risk estimates. However, the uncertainties in risk estimates can be large (orders of magnitude) when the data gaps are significant. Moreover, for some data gaps--such as the lack of information on interactive effects of multiple carcinogens consumed in the real world--risk assessment traditionally cannot consider these problems. As the National Academy of Sciences has made clear, in many ways standard risk assessments may seriously underestimate risks, particularly for infants and children. Among the most important sources of uncertainty and possible underestimation of risks in classic food safety risk assessments are:

Interactive Effects: Complex Mixtures of Pesticides and Other Toxins

- o Unlike laboratory rats, people generally go through their lives breathing, eating, and drinking an extraordinarily complex mixture of toxic and potentially carcinogenic substances, both natural and anthropogenic. For example, pesticide residue data indicate that in a single meal, a person can easily consume five, ten, or more pesticide residues in his or her food.
- o The cumulative toxicological effects of pesticide active ingredients, "inert" ingredients, and other carcinogens from multiple sources should be considered, but are not.
- o Good science would dictate that the real world of exposure to complex mixtures must be the basis of our pesticide policies. Yet synergism, additivity, and other possible joint effects of carcinogens in foods generally are not considered in risk assessments. Scientific literature indicates that in some cases, such as with asbestos and smoking, radiation and smoking, or smoking and alcohol, synergism of carcinogenic effect have been shown; in other cases, additivity or other interactive effects are found.
- o Synergistic effects of pesticides to animals as acute toxins (e.g. malathion and EPN) have been shown in well-documented toxicological studies, but few if any studies have sought to document whether pesticides have additive, synergistic, or

antagonistic effects in causing cancer.¹ Pesticide users and registrants sometimes rely upon and use synergistic toxic effects of two or more pesticides in controlling pests by applying more than one pesticide at once (known as "pesticide synergists"), to get more than an additive "kill."² There is no a priori reason to suspect that synergistic toxic effect is necessarily limited to target organisms.

Underestimates of Risks to Children, Minorities, the Poor, and Other Subpopulations Due Consideration of "Average" Consumers and Gaps in Exposure Data

- o Accurate data regarding the true levels of exposure of all important subpopulations to individual pesticides and on exposure to complex mixtures of pesticides and other carcinogens, are virtually impossible to obtain. Thus, traditional risk assessment sets levels based on "average" consumers--failing to protect the most exposed subpopulations.
- o Exposure to each pesticide from all media and sources, such as commercially purchased food, sport fish, drinking water, air drift, indoor and outdoor air pollution, occupational exposure, and so forth, ideally should be considered, but generally are not. Often data on key subpopulations' actual exposure is virtually nonexistent so accurate risk assessment for those people is impossible.
- o As the National Academy of Sciences pointed out, children tend to eat large amounts of certain foods--in many cases an order of magnitude or more larger amounts of some foods such as certain fruits and juices. Thus, pesticide residues on those foods pose a disproportionately high risk to children.
- o Some population subgroups, such as members of certain ethnic or religious minorities who eat a disproportionately large amount of certain foods, also may be at especially high risk.

¹See, e.g., Doull, J., Klaassen, C.D., & Amdur, M.O., Casarett and Doull' Toxicology: The Basic Science of Poisons (Macmillan, Second Edition, 1980); Murphy, S.D., Costa, L.G., & Schwab, B.W., "Pesticide Interactions and Development of Tolerance," in Effects of Chronic Exposures to Pesticides on Animal Systems, J.E. Chambers & J.D. Yarbrough, eds., pages 227-241 (Raven, 1982).

²Hayes, W.J. & E.R. Laws, Jr., Handbook of Pesticide Toxicology, vol. 3, 1508-1510 (Academic Press, 1991).

- o The National Academy of Sciences report on children and pesticides pointed out that children living in poverty may be at special risk due to higher exposure to toxins in more polluted neighborhoods, poor nutrition, and otherwise compromised health.¹³ Thus, the Academy noted, "the combined effect of poorer health status and of likely higher exposure to environmental toxicants suggests that the further burden of pesticide exposure [to poor children] could lead to toxic effects that do not produce effects in other children. Therefore, one might expect that adverse effects of pesticides, whether acute or chronic, might be magnified in this subpopulation."¹⁴
- o There may be "foodsheds," or areas of the country where people tend to eat fresh commodities primarily from local growers. Those who often eat local fresh foods soon after the crop is picked, and who live in regions where crops are more heavily treated with certain pesticides (due, for example, to local climatic or pest infestation conditions), could be exposed to pesticide residues that may be substantially higher than the national average. For example, milk products and many fresh fruits and vegetables may distributed locally almost immediately after they are picked or produced, leaving little time for residue degradation and potentially creating pockets of relatively heavily pesticide residue-laden foods.

Underestimation of Risks Due to Failure to Consider Highly Sensitive Subpopulations

- o Risk assessments generally are not specially designed to discuss or address the risks of pesticide exposure to especially sensitive subpopulations due to their sensitivity: As the National Academy of Sciences has recently emphasized, and as the scientific literature has documented, there are special chemical sensitivities of certain subpopulations, including the young, to certain neurotoxins and other chemicals.¹⁵ Studies also have shown

¹³NAS, NRC, Pesticides in the Diets of Infants and Children, at 343-44.

¹⁴Ibid at 344.

¹⁵See, e.g., National Academy of Sciences, National Research Council, Pesticides in the Diets of Infants and Children (1993); Calabrese, E.J. Age and Susceptibility to Toxic Substances, (John Wiley & Sons, 1986); World Health Organization, Environmental Criteria 59, Principles for Evaluating Health Risks from

(continued...)

that the young are more susceptible to many carcinogens than are adults, due to physiological differences of the young compared to the normal adult population and certain other factors.¹⁵

- o Literature regarding drug and other chemical allergies of certain sensitive individuals suggests that certain subpopulations in the general adult population are especially susceptible to certain chemicals.¹⁶ Pesticides could be among the chemicals to which such allergic or idiosyncratic, highly sensitive reactions may occur.

"Upstream" Effects of Carcinogenic Pesticide Use on Farmers and Farmworkers Are Highly Significant and Often Forgotten

- o A mounting body of epidemiological evidence shows that farmers and farmworkers are at especially high risk of certain cancers associated with their high exposure to certain carcinogenic pesticides.¹⁸

Thus, in many ways risk assessment, due to data gaps, cannot fully consider factors that lead to substantial underestimation of risks. Indeed, many of these factors, such as cumulative, interactive, and synergistic exposure and effects, highly exposed and highly sensitive subpopulations such as children and the poor, and due to the impacts of occupational exposure, there is no real and readily apparent solution that would allow us to say with confidence that a pesticide poses a "negligible risk" in foods even if one accepts that concept as appropriate. Moreover, this approach for foods fails to consider the substantial upstream effects of pesticides on farmers and farmworkers. Therefore, a phase-out of the intentional addition of cancer-causing pesticides to foods, and a phase-in of safer alternatives, is needed.

¹⁵(...continued)

Chemicals During Infancy and Early Childhood: The Need for a Special Approach, (Geneva, 1986).

¹⁶See, Calabrese, supra.

¹⁷See, Casarett & Doull's Toxicology, at 15-16.

¹⁸For a summary of some of this evidence, see, M. Moses, "Cancer in Humans and Potential Occupational and Environmental Exposure to Pesticides: Selected Epidemiological Studies and Case Reports," AAOHN Journal, v. 37, p. 131-36 (March, 1989); NRDC, After Silent Spring: The Unsolved Problems of Pesticide Use in the United States, pp. 8-14 (June, 1993).

A Review of Real World Exposure to Multiple Pesticide Residues and Other Potential Carcinogens from Multiple Sources

It is important to recognize that generally, when we discuss the risks of a pesticide on food, we are discussing only a very narrow subset of the risks. Moreover, as noted above, EPA's risk assessments for pesticides generally calculate cancer risks assuming that a person is exposed to one pesticide at a time.

In contrast, in the real world we are all exposed to a complex mixture of carcinogenic pesticides and other cancer-causing chemicals. Generally, EPA has not sought to evaluate the cancer risks posed by the use in the food supply of not just one pesticide but the nearly 300 "active ingredients" (and an imperfectly examined large number of "inerts," i.e., "inert" as far as target pests are concerned, although many of these "inert" chemicals are quite humanly "active"). EPA has said that approximately 70 pesticides now in use on food are probable or possible human carcinogens. Many experts are concerned that this percentage will grow when reregistration is complete.

It also is important to recognize that food-use chemicals are, of course, not the only pesticides to which people are exposed, nor is food the only route of exposure to food use pesticides. Many of us live, work, and recreate in locations in which pesticides are used and to which we may be exposed by breathing, dermally, and in our drinking water. Moreover, there are 53,000 chemicals used commercially in the U.S.; for 86% of these, we do not have even modest toxicological data upon which to base any assessment of safety, acute, chronic, or otherwise.^{\2} Examining a subset of the 14% of the non-pesticide chemicals for which some toxicological data exist, we find many more suspect carcinogens. For example, cosmetics contribute another 125 possible or probable human carcinogens.^{\10} In addition, there are numerous airborne carcinogens, carcinogens in drinking water (i.e., that which we combine with our food when we cook it),^{\11} in the work place, in drugs, in tobacco, and so

^{\2}Grisham, Health Aspects of the Disposal of Waste Chemicals, 182 (1986) (hereafter, "Grisham").

^{\10}Hutt & Merrill, Food and Drug Law, 819 (2d ed. 1991).

^{\11} As of 1981, the National Academy of Sciences had identified at least 21 carcinogens in drinking water. Hoel & (continued...)

forth. The levels of exposure to carcinogens in these other media (especially in the work place) are often greater by several orders of magnitude.¹²

Risk assessments in the pesticide food safety arena generally fail to consider this reality. It is rarely, if ever, explicitly emphasized, that a 1/1 million risk cited for a carcinogenic pesticide on food is derived from animal experiments in which the animals are knowingly exposed to no other carcinogens other than the one in question.¹³ By contrast,

¹¹(...continued)

Krump, "Water Borne Carcinogens: A Scientist's View," in Crandall & Lave, eds., *The Scientific Basis of Health and Safety Regulation*, at 173, 180-82 (1981). "Estimates of the risks [of each these individual carcinogens] were obtained from controlled animal studies and apply specifically to risks of chemicals in the absence of other carcinogens. The magnitude of such effects cannot be predicted from data on individual carcinogens." *Id.* at 182. "[A]dding these weighted risks together would yield an estimate of the total carcinogenic effect of these chemicals. However, this would probably underestimate the total carcinogenic risk from drinking water since the estimate would not include the carcinogenic potential of the chemicals in drinking water not yet identified or not yet tested for carcinogenicity. Approximately 90 percent of the total organic content in drinking water falls into this category." *Id.* at 182-83.

¹² Generally, exposure to carcinogens on the job is permitted at a much higher level than in food. For example, OSHA allows exposure to arsenic at a level that results in a QRA of 8,000 lung cancers per million exposed workers. ASARCO v. OSHA, 746 F.2d 483 (9th Cir. 1984); Hutt & Merrill, supra, at 938. Persistent low level exposures may be worse than intermittent or single exposures at a higher level. Yet, there is substantial scientific support for the "one-hit" theory--that under some circumstances, a single exposure to some carcinogens is enough to cause cancer. See e.g., Scheuplien, "Risk Assessment and Food Safety: A Scientist's and Regulator's View," 42 Food, Drug & Cosmetic Law Jour. 237, 241 nn. 15 & 16 (1987).

¹³ The comprehensive NAS report, Complex Mixtures: Methods for In Vivo Testing, (1988) (hereafter "NAS, Complex Mixtures") at 5, explains why:

Toxicity testing has traditionally studied chemical compounds one at a time, for various reasons: dealing with agents singly has been more convenient to investigators;
(continued...)

humans are potentially exposed to more than 60 carcinogens just in food (a number that likely will increase when all the toxicological data come in).¹⁴

The introduction to a recent IARC symposium on the subject pointed out that "[m]ost chemical exposures in the real world involve complex mixtures rather than single agents, but the scientific data-base for these mixtures is generated almost

¹³(...continued)

physicochemical properties of single agents were often more readily defined; dosage could be more easily controlled; biological fate could usually be monitored in a straightforward manner; concentrations in air, water, and tissue could be accurately measured; target-organ toxicity was predictable on the basis of experience with agents related to the one in question; and relevant data were often available from human occupational exposures.

¹⁴NAS, Complex Mixtures, at 1, begins as follows: "People are seldom exposed to single chemicals. Most substances to which people are exposed, whether naturally or artificially produced, are mixtures of chemicals. Mixtures that are of particular concern include chemicals generated in fire, hazardous wastes, pesticides, drinking water...."

FDA has recognized that "[t]he approval of a carcinogen[] does not include consideration of the potential interaction or synergy between an approved compound and any other substance or substances to which people are exposed. Certainly, the more approved carcinogenic compounds that are marketed the greater is the likelihood of cancer induction in people." 50 Fed. Reg. 45530 (10/31/85), quoted in Hutt & Merrill, supra, at 900-01 (emphasis added). This notion was emphasized in, Environ Corp., Elements of Toxicology and Chemical Risk Assessment: A Handbook for Attorneys and Decision Makers (1986), at 53 (emphasis added):

The basic problem can be stated simply: we can measure the risks posed by chemicals only under certain highly restricted conditions of exposure, but we need knowledge of (i.e., [we need to] assess) the risks they may pose under conditions of exposure that fall out of the range of current measurement capabilities....The most serious potential danger associated with the use of risk assessment concerns the failure to recognize its limitations and uncertainties."

entirely from studies of individual agents." ^{\15} While it is indeed true that "[e]stimating the human cancer risks of exposure to complex mixtures presents formidable methodological problems..., such exposures are thought to account for a large proportion of cancers, in particular because of widespread exposures to such mixtures within populations." ^{\16}

In short, "good science" should emphasize and do its best to account for the reality that in contrast to laboratory animals, humans are exposed to a multiplicity of carcinogens, a reality that implicates the very important concept of toxic interaction. As one expert in the area notes:

A toxic interaction is defined as a condition in which two or more chemicals result in a qualitatively or quantitatively altered biological response relative to that predicted from the action of the individual chemicals. For any exposure, both exogenous and endogenous interactions may result in either: (a) additivity--where the combined effect is the sum of the effects of the individual agents; (b) synergism--where the combined effect is greater than the sum of the effects of the individual agents; (c) potentiation--where one component enhances the effect of the other [e.g., carcinogenic promoters and initiators]; or (4) antagonism--where the combined effect is less than the sum of the effects of the individual agents. ^{\17}

The effect will vary, depending upon the particular chemicals in question. Indeed, the effect can vary with the same chemical; if

^{\15}Viviano, Sorsa, & McMichael, Complex Mixtures and Cancer Risk, 1 (WHO, IARC 1990) hereafter cited as "IARC, Complex Mixtures".

^{\16}Id. at 8.

^{\17}Grisham, at 183. See also, NAS, Complex Mixtures, 1-29, 185-201; Kaldor & L'Abbe, "Interaction Between Human Carcinogens," and Williams, "Chemical Mixtures and Interactive Carcinogenesis: In Vitro Studies," in IARC, Complex Mixtures, at 35-43, 107-12; Murphy, "General Principles in the Assessment of Toxicity of Chemical Mixtures," 48 Environ. Health Perspectives, 141-44 (1983); Chen, Gaylor & Kodell, "Explanation of the Joint Risk from Multiple-Compound Exposure Based on Single-Compound Experiments," 10 Risk Analysis 285 (1990); Calif. Dept. of Health Services, Guidelines for Chemical Carcinogen Risk Assessments and Their Scientific Rationale, p. B-7 (1985).

exposure to chemical A precedes exposure to B, the effect can be different than if the exposure is the other way around.¹⁸

¹⁸ "Both the sequencing and the frequency of events in a combined exposure may contribute to the mechanism of toxic interaction. The interaction between chemicals and multiple environmental factors can result in an increase in the incidence of some human cancers that is greater than that expected from an exposure to a single carcinogen. The chemical induction of tumors is considered to be a multi-stage phenomenon, requiring either repetitive exposure to a single agent followed by promotion from a secondary agent at a later time. Initiation takes place rapidly and is considered to be essentially irreversible, while promotion may occur months or even years later." (Grisham, at 183-84 (citations omitted))

In addition, "[i]t is commonly believed that....the theoretical effect of two carcinogens acting at different stages can be substantially altered by the timing of the two exposure periods, resulting in a spectrum of risks ranging from additive to greater than multiplicative." (Brown & Chu, "Additive and Multiplicative Models and Multistage Carcinogenesis Theory," 9 Risk Analysis, 99 (1989).)

"The concepts of initiation and promotion were derived from empirical observations of experimental tumorigenesis....in which the administration of an ineffective dose of a known carcinogen, followed by repetitive treatment with another agent [a non-carcinogenic promoter] elicits the appearance of many tumors. Application of this second agent alone causes only a few tumors." (Trosko & Chang, "Role of Tumor Promotion in Affecting the Multi-Hit Nature of Carcinogenesis."

"The concepts of initiation, promotion, and progression have evolved to explain the observation that tumors could be induced by application of a subthreshold dose of a carcinogen (the initiation phase) followed by repetitive treatment with a noncarcinogen (the promotion phase)." Id. at 262. "If PBB is given to a rat prior to administration of a carcinogen, for example AAF or DMBA, it will actually protect the animal from the initiating potential of these particular compounds. The same compound, given in the exact same way, but after initiation, acts as a promoter. Here we have a real dilemma in that it is going to be impossible to put a red flag or green flag on a molecule just by virtue of its structure. We have to make our assessment in the context of the biological behavior of the compound. Why [are] these kinds of chemicals acting as anti-initiators under one set of conditions, and as anti-promoters in one organ system, but as promoters in another organ system of the same species?" (continued...)

One study was conducted, for example, on the acute toxic interactions of 13 organophosphorous pesticides. The investigators found that 21 pairs had additive toxicity, 18 pairs had less than additive toxicity, and four pairs had synergistic toxicity.^{\19}

To get out of the conceptual realm and into reality, that is, to determine the actual interactive effect of a given pesticide, at the most extreme, it would be necessary to conduct separate animal feeding tests with it, plus one other, through the 60,000 other chemicals presently in use. The cost of doing these experiments would be astronomical. But even then, bearing the costs would only tell us more about the interactive effect of two chemicals. The costs of conducting the tests for combinations of 3, 4, 5, 6, etc. chemicals make such testing unrealistic.^{\20}

Conclusion

Thus, there are major uncertainties using quantitative risk assessment for pesticides, ranging from the inability to grapple with cumulative and interactive effects of the pesticides we are exposed to daily, the impacts on especially sensitive subpopulations such as children and especially poor children, the lack of exposure data for key subpopulations, and the failure to consider "up stream" effects on workers and farmers. Therefore, without the ability to pinpoint with accuracy the actual level of risk posed by cancer causing pesticides, a "pollution prevention" approach that seeks to cut off the problem at its source through the phase out of the carcinogens and phase in of alternatives is vitally important.

^{\18}(...continued)

Id. at 284

"A single promoter has been shown to intensify the effects of a particular carcinogen by a factor of 1,000." Page, Harris, and Bruser, "Waterborne Carcinogens: An Economist's View," in Crandall & Lave, supra, n. 1, at 197, 201, citing Bingham & Falk, "Environmental Carcinogens: The Modifying Effects of Carcinogens on the Threshold Response," 19 Arch. of Environ. Health, 779-83 (1969).

^{\19}Casarett and Doull's Toxicology, supra, at 398.

^{\20} Testing all of the interactions between just 10 chemicals would require 1,013 tests. See the EPA-sponsored NAS study, Drinking Water and Health: Selected Issues in Risk Assessment, vol. 9, pp. 121-22 (1989).

Executive Summary

Agriculture is vital to the American economy. Production, sale, and processing of food and fiber constitute 17 percent of the United States gross national product. Dramatic increases in agricultural productivity have occurred as a result of applications of pesticides and fertilizers, high-yielding crop varieties, and irrigation. The use of nitrogen fertilizers has increased almost three-fold since the 1960s. Similarly, pesticides applied to major crops such as cotton, corn, rice, soybeans, and wheat increased 175 percent between 1964 and 1982.

While increasing the abundance and diversity of our food supply, the widespread use of agricultural chemicals has not occurred without serious environmental, social, and economic costs. During the past decade, the public has focused much of its attention on the issue of pesticides in food. Yet environmental contamination by agricultural chemicals, particularly of ground and surface water supplies, may be a more serious and pervasive problem in the long term.

Agricultural Contamination of Water Resources

Recent results of the U.S. Environmental Protection Agency's (EPA) National Pesticide Survey indicate that nitrate is one of the most common contaminant of groundwater and is present in 52 to 57 percent of community and private wells nationwide. The survey also estimates that ten percent of community wells and four percent of rural domestic wells contain at least one pesticide, resulting in at least 1.3 million people drinking from contaminated wells. Another EPA database indicates that a total of 46 different pesticides have been detected in the groundwater of 26 different states as a result of normal agricultural use. Once contaminated, it is often technically and economically infeasible to restore groundwater to its original condition. The U.S. Department of Agriculture's (USDA) Economic Research Service estimates that first-time monitoring costs, the first step in remediation, of private and community wells for pesticides and nitrate in potentially contaminated areas would exceed \$1.4 billion.

Surface waters can also be contaminated with nitrate and pesticides. A 1989 survey by the U.S. Geological Survey detected herbicides in 90 percent of streams in ten midwestern states after agricultural applications. The Iowa Department of Natural Resources tested surface waters and found that 90 percent of the samples contained pesticide residues even after drinking water treatment. Eighty-two percent of the supplies tested contained multiple pesticide residues.

Pesticides have also been detected in rainwater and fog. Since 1987, a total of ten herbicides and four insecticides have been routinely detected in Iowa rainwater. Recent monitoring has found residues of four organophosphate insecticides in winter fog in California's Central Valley.

The Limits of Current Law and Public Policy

A variety of federal statutes have been enacted in the past two decades to protect and enhance the quality of water resources. The Clean Water Act requires general water pollution controls. The quality of drinking water is specifically addressed in the Safe Drinking Water Act. The Resource Conservation and Recovery Act establishes requirements for the treatment, storage, and disposal of hazardous wastes. The Comprehensive Environmental Response and Liability Act, or Superfund, authorizes the federal government to clean up contamination caused by inactive waste disposal sites or spills, and imposes strict liability for cleanup on private companies whose past disposal practices have resulted in environmental contamination. Many states also have laws to protect water quality. Unfortunately, both federal and state laws have generally failed to adequately address agriculture's role in water quality degradation. Furthermore, the Federal Insecticide, Fungicide, and Rodenticide Act, the fundamental federal law that regulates the sale and use of pesticides, does not specifically address pesticide pollution of water supplies.

Despite these numerous laws, widespread and significant agricultural contamination of ground and surface waters continues with potentially serious consequences for public health. Exposure to nitrate in drinking water can cause "blue-baby syndrome," a potentially fatal condition in infants. Pesticides that have been found in ground and surface water are known or suspected to cause cancer, birth defects, damage to the nervous system, and other health effects.

The Promise of Alternative Agriculture

The lack of national leadership to protect water resources from agricultural nonpoint source pollution, combined with the additional threats pesticides pose to the environment and public health, provides a strong argument for reducing the use of agricultural chemicals. Source reduction, as in other industries, is a logical, practical strategy for preventing the environmental problems associated with agriculture.

Widespread adoption of alternative agricultural practices holds the greatest potential for source reduction. These farming practices are designed to reduce chemical inputs, preserve and enhance natural resources, and protect human health. Alternative agriculture encompasses practices often referred to as biological, low (or reduced) input, organic, regenerative, and sustainable. Alternative practices contrast with conventional methods of farming that are characterized by intensive cropping systems which rely on synthetic chemical inputs to control pests and maintain soil fertility.

Potential Reductions in Pesticide Applications for Selected California and Iowa Crops

Despite the growing interest in alternative agriculture, broad implementation of these techniques has not occurred. This report seeks to illustrate the dramatic potential for alternative farming systems to reduce pesticide use. By obtaining information on alternative pest control strategies from published scientific literature, results of ongoing research, and experiences of individual farmers, this study projects potential reductions in pesticide applications for nine crops in California and Iowa. These crops were chosen to provide a cross section of the diversity of American agriculture. California, the leading agricultural state in the nation, produces over 50 percent of the nation's fruit and nuts and 47 percent of the nation's vegetables. Five-hundred and eighty million pounds of pesticide active ingredients were sold in California in 1987. Iowa typically produces over 20 percent of the nation's corn crop and ten percent of the supplies traded worldwide. Fifty-seven million pounds of herbicides are estimated to be applied to Iowa cropland each year. Individual crops were selected based on high use of pesticides known or suspected to contaminate water supplies and production in areas considered particularly vulnerable to groundwater contamination.

The viability of alternative farming practices varies depending on weather and soil conditions and the management capabilities of individual farmers. In California alfalfa, border harvesting and strip cutting could potentially reduce insecticide applications by 30 percent. Intercropping of

Potential Reductions in Pesticide Applications

	Insecticide (%)	Herbicide (%)	Fungicide (%)
California			
Alfalfa	30	40	a
Citrus	50	40	a
Cotton	25	b	a
Grapes	35	50	30
Lettuce	25	50	20
Rice	25	50	a
Tomatoes	25	50	b
Iowa			
Corn	80	50	a
Soybeans	b	50	a

* Potential reductions were not estimated because chemical applications were minimal.

* Insufficient information available to estimate potential reductions.

cotton in alfalfa could potentially decrease herbicide applications by 40 percent. Insecticide applications could potentially be reduced 50 percent in San Joaquin Valley citrus with greater adoption of integrated pest management (IPM). "Middles" management in citrus could potentially decrease herbicide applications by 40 percent. In California cotton, insecticide applications could potentially be reduced 25 percent with interplanting and IPM. Leaf removal could potentially reduce fungicide applications by 30 percent in California wine grapes. Insecticide and herbicide applications in California grapes could potentially be decreased by 35 and 50 percent, respectively, with a variety of alternative techniques. In California lettuce, greater use of IPM and crop rotations could potentially reduce insecticide, fungicide, and herbicide applications by 25, 20, and 50 percent, respectively. Adoption of a no-till/drill-seeding system, cover crops, and crop rotations could potentially decrease herbicide and insecticide applications by 50 and 25 percent respectively in California rice. In processing tomatoes, sub-surface drip irrigation, crop rotations, and IPM could potentially reduce herbicide and insecticide applications by 50 and 25 percent. Banding herbicides, ridge-till, crop rotations, and a corn rootworm bait could potentially decrease herbicide and insecticide applications by 50 and 80 percent, respectively, in Iowa corn. In Iowa soybeans, banding herbicides, ridge-till, narrow row production, and strip intercropping could potentially decrease herbicide applications by 50 percent.

Barriers to Alternative Agriculture

Several barriers stand in the way of widespread adoption of promising alternative farming practices. In some areas, a scarcity of skilled labor makes it difficult to follow aspects of IPM that require scouting and other labor-intensive activities. Weather-induced risks, such as heavy spring rains in the Corn Belt, can deter mechanical cultivation. Regional soil conditions can also make it difficult to adopt alternative strategies. For example, the heavy clay soils in certain rice-growing regions of California deter crop rotations.

Federal and state policies also hinder the adoption of alternative farming systems. First, the federal government is the hub of the huge agricultural research and extension complex that spends more than \$1.5 billion each year. Yet alternative agricultural research is underfunded and dissemination of information about these techniques is inadequate. Second, many farmers receive a large portion of their income from farm subsidies disbursed by the federal government. However, the rules by which these payments are distributed prevent reductions in pesticide use by penalizing crop rotations and promoting surplus production and increased yields. Third, federal and state marketing orders and grade standards can result in unnecessary pesticide applications by specifying cosmetic criteria for produce that are difficult to attain cost-effectively without the use of chemicals. Fourth, current pesticide regulations hinder the rapid registration of biologically-based materials that could substitute for chemical pesticides. Fifth, the federal Bureau of Reclamation supplies growers in California and other western states with irrigation water at rates substantially below the true cost. Growers, therefore, are discouraged to invest in water conservation tech-

niques that could facilitate reductions in pesticide use. Finally, the costs farmers now pay for pesticides fail to account for the impact of these chemicals on human health and the environment (so-called externalities). This makes pesticides incorrectly cheaper than alternative farming systems.

Recommendations for Reform

Policy reforms in six key areas are essential for eliminating many of the barriers to widespread adoption of alternative farming systems: agricultural research, federal farm programs, marketing policies, pesticide registration requirements, water pricing, and hidden costs of agricultural chemicals. To date, the development and implementation of agricultural techniques that reduce chemical use have been stymied by the lack of funds directed to alternative agricultural research. Funds for alternative farming research, particularly on-farm, systems-oriented research, should be substantially increased.

The federal farm programs reward farmers for producing a handful of commodity crops that tend to use large amounts of chemical inputs. Commodity programs should be amended so farmers can adopt more environmentally-sound farming systems without incurring financial penalties.

Federal and state marketing policies often make it difficult for farmers to adopt alternative farming practices that use fewer pesticides. Federal and state marketing orders should not be allowed to use cosmetic quality standards to differentiate produce. In addition, exemptions from marketing orders should be granted to all certified organic produce.

The development of biologically-based materials, such as botanicals, microbials, and pheromones has been obstructed by federal and state pesticide registration requirements. Congress should direct the National Academy of Sciences to review existing regulations for biologically-based materials and make recommendations for improving government procedures to hasten the registration of biologically-based pest control techniques.

The use of efficient irrigation systems has the potential to significantly reduce the use of agricultural chemicals and their transport to water supplies. However, because of the low price of irrigation supplies available to many growers, more efficient technologies and management practices have not been widely adopted. The U.S. Bureau of Reclamation should revise its water prices to encourage greater efficiency. Similarly, irrigation districts should adopt tiered water rate schedules that discourage inefficient irrigation practices and encourage the adoption of alternative farming systems.

Conventional agricultural practices rely extensively on the use of pesticides and fertilizers. However, current market prices for pesticides and fertilizers do not reflect the true environmental and social costs of their use. Federal and state governments should levy fees on the use of pesticides and fertilizers to reflect the environmental and health costs, and to provide revenues for alternative agricultural research and development programs, as is the current case in Iowa.



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Testimony of the
 National Cotton Council of America
 presented to
 Subcommittee on Department Operations and Nutrition
 Committee on Agriculture
 on Administration's Pesticide Reform Proposal
 June 15, 1994

The National Cotton Council appreciates the opportunity to present testimony to the Subcommittee on Department Operations and Nutrition regarding food safety issues and the Administration's pesticide reform proposal.

The National Cotton Council is the central organization of the U.S. cotton industry. Membership includes producers, ginner, warehousemen, merchants, oilseed crushers, cooperatives and textile manufacturers. Most of the industry concentrates in 17 cotton-producing states, reaching from Virginia to California. The downstream manufacture of cotton apparel and home furnishings and of cottonseed products, however, occurs throughout the nation.

While cotton's annual farm gate value is a significant \$5 billion, perhaps a more meaningful measure of the industry's value to the U.S. economy is its retail impact. The business revenue generated annually by cotton and its products exceeds \$50 billion. Cotton stands above all other field crops in its creation of jobs and its contribution to the U.S. economy. The industry, its suppliers and the manufacturers of cotton and cottonseed products, account for 1 of every 13 jobs in the workforce.

The Council commends the Administration for its hard work in developing pesticide reform legislation. The issue of food safety is complex and any attempt to change the present law will have far reaching consequences, especially in the area of risk benefit analysis. We have concerns about many of the provisions in the Administration's bill and therefore cannot support it.

Our concerns about the Administration's proposal include provisions which address: (1) the way pesticide safety standards are set -- the Administration's bill would impose an unrealistic conservative and all too rigid safety standard for pesticide tolerances. (2) The methods of assessing products already on the market -- phase-out orders could empower

EPA to limit or prohibit the use of pesticides without the external scientific review and procedural protection guaranteed under the cancellation process, and without any consideration for the pesticide's benefits. (3) Requirements for multiple tolerances -- EPA would be authorized to set unnecessary multiple tolerances for a pesticide on a single food at different points in the distribution chain. (4) Expanded recordkeeping requirements -- EPA would also have the authority to add more requirements to the present recordkeeping program and inspection procedures on pesticide user premises. (5) Enforcement policies -- FDA is granted broad new enforcement power, including recall, embargo and civil penalty authority with respect to pesticide tolerance violation. And most importantly, (6) provisions relating to consideration of risks and benefits -- "health benefits" would not include benefits from an adequate, wholesome or economical food supply.

Addressing risk and preserving benefits are essential components to any credible food safety law or regulation. The Administration's proposal limits and eventually eliminates benefit considerations for tolerances and a rigid negligible risk standard for tolerances is established. This is of great concern to our organization.

The American consumer has access to the most abundant, nutritious and affordable supply of food and fiber in the world. The benefits derived from this food and fiber supply are essential to a healthy diet and the health of our economy. The contribution that farmers make to feeding and clothing our nation as well as others in the world is significant. Most farmers use only inputs that are necessary to produce the crop, and new techniques have been introduced in all areas of crop production.

However, American consumers seem to be increasingly concerned about the safety of their food. Part of this concern may be explained by distance and dependence. As the farm population shrinks to about 2% and more and more of our citizens depend on others to grow and prepare their food, their understanding of farming practices and food production has decreased. This may result in a decrease of confidence in the safety of our food supply.

To some extent, this has been exploited and scare tactics have been employed whereby the public becomes confused and misinformed about important issues. For example, we are all familiar with the controversies associated with Alar on apples and the use of irradiation in food processing.

Agricultural production has undergone a radical transformation in the last 30 years, especially in the area cotton production. For example, field preparation practices reflect the varied environments and production systems encountered across the U.S. growing regions. Conservation tillage systems are gaining in popularity in areas subject to soil erosion. Conservation tillage, which includes, minimum till, no till and other forms of maintaining residue on the soil surface, has enabled farmers to increase their production options in response to their specific challenges. These systems became feasible with the

advent of specialized equipment and new herbicide chemistry that reduce or eliminate the need for extensive tillage.

Integrated Pest Management is practiced throughout the U.S. cotton belt. This approach optimizes the total pest management system by utilizing all available tools, including rotation, crop residue destruction, maximum crop competitiveness, earliness, pest scouting, action thresholds and high selective crop protection chemistry. New chemicals coupled with good IPM schemes are helping to reduce grower reliance on prophylactic, protective treatments in favor of responsive, as-needed treatments. Insect management continues to evolve as selective chemistry and Bt transgenic cottons reach commercialization.

Also, cotton fertilization practices have undergone dramatic changes in recent years. Supplying nutrients as the crop demands has replaced traditional methods, as soil and tissue testing have become widespread.

The Council supports H.R. 1627, the bill introduced by Representatives Lehman, Bliley, and Rowland and cosponsored by over 218 members of the U.S. House of Representatives. We believe that the provisions in this bill give regulators the flexibility that they need to apply the latest scientific data and technology to pesticide standards. The Delaney paradox is addressed by establishing a single, flexible negligible risk standard for pesticides residues in raw commodities and processed food. National uniformity is provided for setting tolerances and the pesticide cancellation and registration process is streamlined. However, what is most important is that benefits are considered when weighing risks.

Provisions in this bill allow EPA to consider benefits in setting tolerances for pesticide residues on raw commodities and would extend that power to tolerances for pesticide residues on processed food. EPA would be directed to take into account health, nutritional and consumer benefits, including the impact of loss of a pesticide on the availability of an adequate, wholesome and economical domestic food supply.

The importance of these benefits should not be underestimated. All American consumers should be able to purchase food that is safe, nourishing, and affordable. Furthermore, a realistic assessment of risks and benefits should be part of all food policy.

We believe that the provisions in H.R. 1627 support these goals and we urge Congress to act on this legislation and its companion bill, S. 1478, introduced by Senators Pryor and Lugar as soon as possible.

CONGRESSMAN J. ROY ROWLAND
BEFORE THE SUBCOMMITTEE ON DEPARTMENT
OPERATIONS AND NUTRITION
HEARING ON H.R. 1627
THE FOOD QUALITY PROTECTION ACT
JUNE 15, 1994

Mr. Chairman, I commend you for holding this hearing today. I think that we can all agree that our current pesticide laws are in need of updating. I am pleased to be involved in this debate as one of the main cosponsors of H.R. 1627, the Food Quality Protection Act. I want to thank my fellow cosponsors, Congressman Lehman, who is the main sponsor of this legislation, and Congressman Bliley for all of their work on this bill. H.R. 1627 will, among other things, reform and modernize the pesticide risk tolerance provisions of the Federal Food, Drug and Cosmetic Act (FFDCA).

The U.S. food supply is the safest, most wholesome and abundant food supply in the world. Today's foods are safe from pathogens, diseases, and parasites, and are more nutritious than ever. Pesticides and fertilizers are crucial to the production of our high quality food supply.

We can all agree that improvements are needed as highlighted by a recent study by the National Academy of Sciences on pesticides and children. As a practicing physician for 28

years, I, too, am concerned about the health of our children. It is important to note that Dr. Philip Landrigan, who headed the NAS study, stated that the wholesale banning of pesticides as a result of this study is inappropriate, and that what is required is better management of pesticide risks. That is exactly the intention of H.R. 1627, which provides the EPA with tools that it now lacks to better regulate the use of pesticides, and the presence of pesticide residues.

As most of us are aware, a recent circuit court decision upheld the "Delaney Clause" and took away EPA's discretion to use a "negligible risk" standard. As a result, EPA has threatened to ban 35 invaluable and widely used pesticides. The loss of these pesticides could increase the costs of production for producers and the costs of commodities for consumers. The availability and quality of foods for consumers would decrease as well.

The loss of these pesticides would be devastating to the South and Southeast. The production of fruits and vegetables would decrease; peanut production would be disabled; and, the costs of soybean production would skyrocket. This would be disastrous in my own State of Georgia.

The Food Quality Protection Act will address this problem. The bill will improve and update current law and will give EPA the necessary flexibility to employ reasonable risk assessments. It will streamline the pesticide cancellation process and provide a uniform negligible risk standard for pesticide residues in both raw and processed foods.

While I appreciate the efforts of the Administration to reform the food safety laws with its legislative proposal, I believe that their bill ignores the need for reasonable risk assessment. I look forward to working with our fellow Members of Congress and the Administration on this important issue. I urge my colleagues to strive for a rational solution to the reform of the food safety standards. Thank you for the opportunity to testify.



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